
# IVAX Diagnostics, Inc.





# 2001 Annual Report

IVAX Diagnostics, Inc.

June 25, 2002

# To Our Shareholders

We are pleased to send you the first annual report for IVAX Diagnostics, Inc. In March of last year, IVAX Diagnostics, then a wholly-owned subsidiary of IVAX Corporation, merged with b2bstores.com Inc. Today, we are a vertically integrated company operating in the $22 billion world diagnostics market through three separate subsidiaries Diamedix Corporation, based in Miami, Florida; Delta Biologicals, S.r.l., located near Rome, Italy; and ImmunoVision, Inc., based in Springdale, Arkansas. Through these three companies, we offer a combination of diagnostic test kits and instrumentation that allows laboratories to test for autoimmune disorders and infectious diseases. We plan to provide innovative and proprietary testing systems throughout the world in the immunology market sector (including, among others, testing for allergies, tumor markers, hormones, HIV and hepatitis) enabling laboratories to perform laboratory testing in an efficient and automated manner.

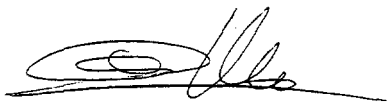
During the past year we successfully introduced 8 new FDA-cleared autoimmune and infectious disease test kits that can be run manually or in combination with our Mago® Plus automated immunoassay analyzer. This now gives us a total of 42 tests, which positions us to market this system through our direct sales force in the United States and Italy and through independent distributors in other markets throughout the world. We have also strengthened our distribution network during the year by adding distributors in Japan, China, Australia, New Zealand, Venezuela, Mexico, Portugal, and Spain. We believe our direct sales effort has been very effective and we are continuing to increase the number of sales personnel we are employing. We believe that these efforts will allow us to continue to achieve additional market share with our automated test systems.

Despite our sales growth in the United States from Mago® placements, our efforts in 2001 were negatively impacted by decreased sales of instrumentation to Sigma Diagnostics, our largest customer during the past three years. We believe this situation has been resolved through our acquisition of Sigma Diagnostics' enzyme immunoassay (EIA) product line, which we announced last month. As a result of the acquisition, we intend to sell EIA instrumentation and reagents directly to the customer base previously established by Sigma Diagnostics. Consequently, we expect that our acquisition of Sigma Diagnostics' EIA product line will have a positive impact on future financial results, including, among other things, by favorably impacting our gross margin by lowering our kit production costs.

We expect our future growth will come as a result of internal developments as well as additional strategic acquisitions and technology agreements. We are currently working diligently toward the development of a new instrument system at our facilities in Italy, which we believe will allow us to include additional testing sectors within the diagnostics market beyond the autoimmune and infectious disease areas that we have focused on to date. We continue to seek new acquisition opportunities and to pursue strategic agreements that will make new assays and technologies available to us.

We thank all of our customers, employees, and shareholders for your support of IVAX Diagnostics during this dynamic stage of our development.

Phillip Frost, M.D.
Chairman of the Board of Directors



Giorgio D'Urso
President and CEO

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 10-K

## ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

**For the fiscal year ended December 31, 2001**

**Commission File Number 1-14798**

# IVAX DIAGNOSTICS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **11-3500746** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |

**2140 North Miami Avenue, Miami, Florida 33127**
**(Address of principal executive offices, including zip code)**

**(305) 324-2300**
**(Registrant's telephone number, including area code)**

**Securities Registered Pursuant to Section 12(b) of the Act:**

| **Common Stock, Par Value $0.01** | **American Stock Exchange**<br>**Boston Stock Exchange** |
|---|---|
| **(Title of class)** | **(Name of each exchange on which registered)** |

**Securities Registered Pursuant to Section 12(g) of the Act: None**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

The aggregate market value of the voting common stock held by non-affiliates of the registrant on March 20, 2002, was approximately $25,906,956 million.

As of March 20, 2002, there were 28,635,652 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

None

**IVAX DIAGNOSTICS, INC.**

**Annual Report on Form 10-K**
**for the year ended December 31, 2001**

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# PART I

## Item 1. *Business*

### Cautionary Statement Concerning Forward-Looking Statements

We have made forward-looking statements, which are subject to risks and uncertainties, in this annual report on Form 10-K. These statements are based on the beliefs and assumptions of our management and on the information currently available to it. Forward-looking statements may be preceded by, followed by, or otherwise include the words "believes," "expects," "anticipates," "intends," "plans," "estimates," "projects," "would," "should," or similar expressions or statements that certain events or conditions "may" occur. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on our expectations and the beliefs and assumptions of our management and on the information currently available to it and are subject to a number of risks and uncertainties, including, but not limited to, the risks and uncertainties associated with: economic, competitive, political, governmental and other factors affecting us and our operations, markets and products; the success of technological, strategic and business initiatives; our limited operating revenues and history of operational losses; our agreements with IVAX Corporation, or IVAX, third party distributors and key personnel; consolidation of our customers and reimbursement policies of governmental and private third parties affecting our operations, markets and products; price constraints imposed by our customers, governmental and private third parties; our reliance on our largest customer; our ability to consummate potential acquisitions of businesses or products including the proposed acquisition described below, and if that acquisition is not consummated that we may have no remedies available against our largest customer under the agreements we have with them; our ability to integrate acquired businesses or products; political and economic instability and foreign currency fluctuation affecting our foreign operations; the holding of substantially all of our cash and cash equivalents at a single brokerage firm, including risks relating to the bankruptcy or insolvency of such brokerage firm; litigation regarding intellectual property rights and product liability; voting control of our common stock by IVAX; conflicts of interest with IVAX and with our officers, directors and employees; and other factors discussed elsewhere in this annual report on Form 10-K. Many of these factors are beyond our control.

### Business

*General.* We are the parent corporation of the following three subsidiaries:

- Delta Biologicals, S.r.l.;
- Diamedix Corporation; and
- ImmunoVision, Inc.

Through these subsidiaries, we develop, manufacture, and market diagnostic test kits, or assays, that are used to aid in the detection of disease markers primarily in the areas of autoimmune and infectious diseases. These tests, which are designed to aid in the identification of the causes of illness and disease, assist physicians in selecting appropriate patient treatment. Most of our tests are based on Enzyme Linked ImmunoSorbent Assay, or ELISA, technology, a clinical testing methodology used worldwide. Specific tests are prepared using a 96 well microplate format whereby specific antigens are typically coated on the wells of a microplate during the manufacturing process. A test using ELISA technology involves a series of reagent additions to the microplate causing a reaction that results in a visible color in the wells. The amount of color is directly proportionate to the amount of the specific analyte in the patient sample. Our kits are designed to be performed either manually or in an automated format. In addition to our line of diagnostic kits, we also design and manufacture laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. This proprietary instrument, named the Mago® system, includes a fully-automated ELISA processor operating with our own user-friendly software, allowing customers to perform tests in an automated mode. We also develop, manufacture, and market raw materials, such as antigens used in the production of diagnostic kits.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy. For additional information about our two segments, see Note 9 to our Consolidated Financial Statements.

Delta, which IVAX acquired in 1991, was established in 1980. From its facility located in Pomezia, Italy, it develops and manufactures scientific and laboratory instruments, including its proprietary Mago® instrument, which includes hardware, reagents, and software. The Mago® system, in association with 74 specific assays acquired from Diamedix and third parties, is sold directly in Italy through Delta's independent sales representatives, most of whom work exclusively for Delta. Delta also sells in Italy other diagnostic products manufactured by third parties. Approximately 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are private laboratories. Thus, sales in Italy are heavily concentrated in the public sector.

Diamedix was established in 1986 after it acquired all of the assets and retained substantially all of the personnel of Cordis Laboratories, Inc., a company that had developed, manufactured, and marketed diagnostic equipment since 1962. IVAX acquired Diamedix in 1987. Diamedix' products are sold in the United States through Diamedix' sale force. Diamedix manufactures 42 assays that the United States Food and Drug Administration, or FDA, has cleared and that are available to be run in conjunction with the Mago® system. These assays are sold under the trade name immunosimplicity®. Diamedix is located in Miami, Florida.

Since 1985, ImmunoVision has been developing, manufacturing, and marketing autoimmune reagents and research products for use by clinics, hospitals, research laboratories, and commercial diagnostic manufacturers. These manufacturers (including Diamedix) use these antigens to produce autoimmune diagnostic kits. IVAX acquired ImmunoVision in 1995. ImmunoVision is located in Springdale, Arkansas.

On March 21, 2002, we announced that we had signed a non-binding letter of intent with Sigma Diagnostics, Inc., a wholly-owned subsidiary of Sigma-Aldrich Corporation, pursuant to which we would acquire Sigma Diagnostics' global enzyme immunoassay product line. The terms of the transaction are being negotiated and there can be no assurance that the transaction will be consummated or that we will be able to successfully integrate the acquired product line. Under previous agreements with Sigma Diagnostics, which are described below, we sold enzyme immunoassay instrumentation and reagents to Sigma Diagnostics which they marketed throughout the world. If the proposed acquisition is consummated, then we will no longer sell reagents or instrumentation to Sigma Diagnostics, which had been our largest customer for the past three years. Instead, we would sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' enzyme immunoassay customer base. If the proposed acquisition is consummated, our previous agreements with Sigma Diagnostics would cease and any issues relating to the relationship of the parties would be resolved. In the event the proposed acquisition is not consummated and Sigma Diagnostics does not fulfill its obligations under its agreements with us, we will review our agreements with Sigma Diagnostics to determine what remedies, if any, we may have. In the event the proposed acquisition is not consummated, there can be no assurance that we be able to replace our largest customer or that any remedies will be available to us in connection with our agreements with Sigma Diagnostics. Any failure to do so or lack of such remedies would have a material adverse effect on our business, prospects, operating results, and financial condition.

*Merger.* On November 21, 2000, IVAX and the pre-merger IVAX Diagnostics, Inc., a wholly-owned subsidiary of IVAX which was incorporated in 1996 by IVAX to be the parent corporation of Diamedix, Delta and ImmunoVision, entered into a definitive merger agreement with us, pursuant to which the pre-merger Diagnostics would merge with and into us, with us as the surviving corporation. The merger was consummated on March 14, 2001, and our name was changed from "b2bstores.com Inc." to "IVAX Diagnostics, Inc." As a result of the merger, approximately 70% of the issued and outstanding shares of our common stock are owned by IVAX and our business has become that of the pre-merger Diagnostics.

We were incorporated on June 28, 1999 under the laws of the State of Delaware. Prior to the merger, we operated an Internet web site that was specifically designed to assist business customers in the operation and development of their businesses. The web site was designed to provide business customers with access to products and supplies, a network of business services and business content. On December 1, 2000, we ceased all web site related operations and permanently shut down our web site.

*Market.* Our products are primarily associated with the in vitro diagnostics market. In vitro diagnostic assays are tests that are used to detect specific substances, usually either antigens or antibodies, outside the body. This usually involves using a blood sample or other bodily fluid sample for testing. The market for in vitro diagnostic products consists of reference laboratory and hospital laboratory testing, testing in physician offices, and over the counter testing, in which testing can be performed at home by the consumer. Industry analysts have stated that the world market for in vitro diagnostics was estimated to be $21.3 billion in 2001 and estimated to grow during the period 2000 to 2005 at a compound annual growth rate of 6%. Of this total $21.3 billion market, the immunoassay world market in which we operate is estimated by industry analysts to be $6.7 billion. We have focused our efforts on what management estimates is a $430 million market for autoimmune and infectious disease immunoassay products. Our ELISA autoimmune product line consists of 21 test kits that the FDA has cleared. These include test kits for screening antinuclear antibodies and specific tests to measure antibodies to dsDNA, SSA, SSB, Sm, Sm/RNP, Scl 70, Jo-1, Rheumatoid Factor, MPO, PR-3, TPO, TG, and others. These products are used for the diagnosis and monitoring of autoimmune diseases, including Systemic Lupus Erythematosus, or SLE, Rheumatoid Arthritis, Mixed Connective Tissue Disease, Sjogren's Syndrome, Scleroderma, and Dermatopolymyositis. Our infectious disease product line includes 21 kits that the FDA has cleared, including Toxoplasma IgG, Toxoplasma IgM, Rubella IgG, Rubella IgM, Cytomegalovirus, or CMV, IgG, CMV IgM, Herpes Simplex Virus, or HSV, IgG, HSV IgM, Measles, Varicella Zoster Virus, or VZV, Lyme Disease, H. pylori, Mumps, six different Epstein-Barr Virus, or EBV, kits and others.

We believe that the market trend for in vitro diagnostic products is towards increased laboratory automation that would allow laboratories to lower their overall costs. We believe that our proprietary Mago® system would enable laboratories to achieve more automation in the autoimmune and infectious disease test sectors.

We are seeking to differentiate ourselves from our competitors through our Mago® instrument. While some of our competitors offer proprietary instruments, other competitors use third parties to manufacture these instruments for them. We believe that the cost advantage we enjoy from our own manufacture of the Mago® instrument, coupled with our production of certain autoimmune reagents at ImmunoVision and our production of diagnostic test kits at Diamedix, positions us to target new product markets for growth beyond the $430 million global market for autoimmune and infectious disease immunoassay products in which we compete. We are currently planning for the release of our next generation Mago® instrument which is expected to be marketed to hospitals, reference testing laboratories, clinics and pharmaceutical, and biotechnology research companies. There is no assurance that this next generation instrument will be successfully launched or produced in commercial quantities, at reasonable costs, and successfully marketed.

*Research and Development.* We devote substantial resources for research and development. For the years ended December 31, 2001, 2000 and 1999, we spent $1.4 million, $1.3 million and $1.2 million, respectively, for research and development activities. There is no assurance that these expenditures will result in the development of new products or product enhancements, that regulatory approval will be obtained or that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed.

Our research and development efforts are targeted towards the development of the next generation Mago® instrument and the development of additional ELISA kits that can be used in conjunction with the Mago® instrument. While there is no assurance that we will be successful, we are seeking to expand the test kits menu we offer in the autoimmune and infectious disease testing sectors and considering moving into additional diagnostic test sectors such as HIV, Hepatitis, and allergy detection.

*Sales and Marketing.* We currently market our products in the United States through our own sales force to hospitals, reference laboratories, clinical laboratories, and research laboratories, as well as to other commercial companies that manufacture diagnostic products. We also sell some of our products to pharmaceutical and biotechnology companies. In addition, some of our products are sold on a private-label basis to other companies that resell the products through their own distribution network. We market our products in certain international markets through a network of independent distributors. We market and sell our products in Italy through a network of 14 salespersons and sales agents, most of whom work on an exclusive basis for Delta. Products are also sold in other global markets through a number of independent distributors. Sales personnel are trained to demonstrate our products, such as the Mago® system, in the laboratory setting. The marketing and technical service departments located in Miami, Florida, Springdale, Arkansas, and Pomezia, Italy support their efforts. We participate in a number of industry trade shows in the United States and Europe.

The products we market are purchased principally by healthcare providers that typically bill third party payors such as governmental programs (e.g., Medicare and Medicaid), private insurance plans, and managed care plans, for health care services provided to their patients. Governmental reimbursement policies are subject to rapid and significant changes in the United States at both the federal and state levels and in other countries. Private third party payors are increasingly negotiating the prices charged for medical products and services. There can be no assurance that healthcare providers will not respond to such pressures by substituting competitors' products for our products. A third party payor may deny reimbursement if it determines that a device was not used in accordance with cost-effective treatment methods, was experimental, or for other reasons. There can be no assurance that our products will qualify for reimbursement by governmental programs in accordance with guidelines established by the Health Care Financing Administration, by state government payors, or by commercial insurance carriers, or that reimbursement will be available in other countries.

In April 1999, we entered into a three year contract with Sigma Diagnostics pursuant to which Sigma Diagnostics agreed to purchase from us a minimum number of scientific instruments per year. Twice during the year 2000, Sigma Diagnostics notified us that it desired to suspend shipments of instruments while our representatives and Sigma Diagnostics' representatives resolved certain product issues. The first suspension lasted for a period of approximately four months. The second suspension began in October 2000 and ended in January 2001. During the last six months of 2001 and to date in 2002, Sigma Diagnostics made no purchases of instruments based upon its determination that it had an adequate level of inventory. In addition, in October 2000, we entered into a three year contract with Sigma Diagnostics pursuant to which we agreed to sell to Sigma Diagnostics certain infectious disease diagnostic kits under a private-label arrangement. Sigma Diagnostics is not required to make a minimum level of purchases under this private-label arrangement. During calendar years 2001, 2000 and 1999 our net revenues from such sales of instruments, replacement parts and diagnostic kits represented 24.9%, 40.1% and 27.8%, respectively, of our total net revenues for such periods.

On March 21, 2002, we announced that we had signed a non-binding letter of intent with Sigma Diagnostics pursuant to which we would acquire Sigma Diagnostics' global enzyme immunoassay product line. The terms of the transaction are being negotiated. Under previous agreements with Sigma Diagnostics, which are described above, we sold enzyme immunoassay instrumentation and reagents to Sigma Diagnostics which they marketed throughout the world. If the proposed acquisition is consummated, then we will no longer sell reagents or instrumentation to Sigma Diagnostics, which had been our largest customer for the past three years. Instead, we would sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' enzyme immunoassay customer base. There can be no assurance that this acquisition will be successfully consummated or that we will be able to successfully integrate the acquired product line. If the proposed acquisition is consummated, our previous agreements with Sigma Diagnostics would cease and any issues relating to the relationship of the parties would be resolved. In the event the proposed acquisition is not consummated and Sigma Diagnostics does not fulfill its obligations under its agreements with us, we will review our agreements with Sigma Diagnostics to determine what remedies, if any, we may have. In the event the proposed acquisition is not consummated, there can be no assurance that we will be able to replace our largest customer or that any remedies will be available to us in connection with our agreements with Sigma Diagnostics. Any failure to do so

or lack of such remedies would have a material adverse effect on our business, prospects, operating results, and financial condition.

Our business is not considered seasonal in nature, but our Italian operations may be slightly affected by the general reduction in business activity in Europe during the traditional summer vacation months.

Our business is not materially affected by order backlog or working capital issues.

*Competition.* We compete on a worldwide basis and there are numerous competitors in the specific market sectors in which we offer our products. These competitors range from major pharmaceutical companies to development stage diagnostic companies. Many of these companies, such as Abbott Laboratories and Pharmacia Corporation, are much larger and have significantly greater financial, technical, manufacturing, sales, and marketing resources than us. The diagnostics industry has experienced considerable consolidation through mergers and acquisitions in the past several years. At the same time, the competition in test sectors such as autoimmune is very fragmented as it is comprised of primarily small companies with no single company possessing a dominant market position. We compete in the marketplace on the basis of the quality of our products, price, instrument design and efficiency, as well as our relationships with customers. In addition to Abbott Laboratories and Pharmacia Corporation, our competitors include DiaSorin, Hemagen Diagnostics, Inc., Sigma Diagnostics, Meridian Bioscience, Inc., Wampole Laboratories (Carter-Wallace, Inc.), Hycor Biomedical, Inc. and Trinity Biotech plc.

The in vitro diagnostic market in which we sell many of our products is highly competitive. The market for our products is characterized by continual and rapid technological developments that have resulted in, and will likely continue to result in, substantial improvements in product function and performance. Our success will depend, in part, in our ability to anticipate changes in technology and industry requirements and to respond to technological developments on a timely basis either internally or through strategic alliances. Several companies have developed, or are developing, scientific instruments and assays that compete or will compete directly with products we market. Many existing and potential competitors have substantially greater financial, marketing, research, and technological resources, as well as established reputations for success in developing, manufacturing, selling, and servicing products, than us. Competitors that are more vertically integrated than us may have more flexibility to compete effectively on price. We expect that existing and new competitors will continue to introduce products or services that are, directly or indirectly, competitive with those that we sell. Such competitors may succeed in developing products that are more functional or less costly than those sold by us and may be more successful in marketing such products. These and other innovations in the rapidly changing medical technology market will negatively affect the sales of the products we market. There can be no assurance that we will be able to compete successfully in this market or that technology developments by our competitors will not render our products or technologies obsolete.

*Personnel.* As of December, 2001, we had approximately 97 full time employees, of whom 16 were managerial, 44 were technical and manufacturing, 11 were administrative, and 26 were sales and marketing.

*Intellectual Property.* In December 1994, Diamedix entered into an intellectual property agreement with two inventors pursuant to which it acquired all rights, title, and interest in the Mago® instrument, including all related software and technical information. Separately, on December 12, 1994, Diamedix entered into consulting agreements with each of the inventors. Only one of these consulting agreements currently remains in effect. Under the terms of the intellectual property agreement, as amended, Diamedix is required to pay the inventors $1,000 per instrument produced beginning with the fifteenth instrument produced, until August 31, 2002, unless the remaining consulting agreement terminates. If the remaining consulting agreement terminates before August 31, 2002, then Diamedix' per instrument payment will cease on the date that such consulting agreement terminates. Alternatively, in lieu of the per instrument payment, Diamedix may, at its election, make a lump sum payment to the inventors equal to $3,000 per instrument produced, beginning with the fifteenth instrument

produced and ending with the last instrument produced, before the date of Diamedix' election, minus all royalty payments previously made to the inventors pursuant to the intellectual property agreement. In the event of breach by Diamedix of the intellectual property agreement, the only recourse available to the inventors is to sue Diamedix for damages. Diamedix would, in any event, retain all right, title, and interest in the Mago® instrument.

The technology associated with the design and manufacture of the Mago® instrument is not protected by patent registrations or license restrictions. The Mago® instrument is our primary product. There can be no assurance that our competitors will not gain access to our proprietary and confidential technologies, or that they will not independently develop similar or competing technologies.

On March 14, 2001, we entered into a use of name license with IVAX whereby IVAX granted us a non-exclusive, royalty free license to use the name "IVAX." IVAX could not terminate this license for a one-year period. After the first year, IVAX may terminate this license at any time upon 90 days' written notice. Upon termination of the agreement, we are required to take all steps reasonably necessary to change our name as soon as is practicable. The termination of this agreement by IVAX could have a material adverse affect on our ability to market our products and on us.

*Governmental Regulation.* The testing, manufacturing, and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA. To comply with FDA requirements, we must manufacture our products in conformance with the FDA's medical device Quality System regulations. Diamedix is listed as a registered establishment with the FDA and Delta has received ISO 9002 certification validating its quality system. The FDA classifies medical devices into three classes (Class I, II or III). Class I devices are subject to general controls, such as good manufacturing practices, and may or may not be subject to pre-market notification. Pre-market notifications must be submitted to the FDA before products can be commercially distributed. Some Class I devices have been deemed exempt from this requirement by the FDA. Class II devices are subject to the same general controls, pre-market notification and performance standards. Usually, Class III devices are those that must receive pre-market approval by the FDA to ensure their safety and effectiveness. Most of our products are classified as Class I or II devices. Generally, before a new test kit can be introduced to the market, it is necessary to obtain FDA clearance in the form of a pre-market 510(k) notification. A 510(k) notification provides data to show that the new device is substantially equivalent to other devices in the marketplace. Almost all of the products sold by us have received 510(k) clearance. In addition, customers using diagnostic tests for clinical purposes in the United States are also regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CLIA is intended to ensure the quality and reliability of all medical testing in laboratories in the United States by requiring that any health care facility in which testing is performed meets specified standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance, and inspections.

Additionally, the products we sell are subject to extensive regulation by governmental authorities in the United States and other countries. Such regulation includes the regulation of the testing, approval, manufacturing, labeling, marketing, and sale of diagnostic devices. Failure to comply with these governmental regulations can result in fines, unanticipated compliance expenditures, interruptions of production, and criminal prosecution. The process of obtaining regulatory approval is rigorous, time consuming, and costly. There is no assurance that necessary approvals will be attained on a timely basis, if at all. In addition, product approvals can be withdrawn if we fail to comply with regulatory standards or if unforeseen problems occur following initial marketing. Domestic and foreign regulations are subject to change and extensive changes in regulation may increase our operating expenses. There can be no assurance that we will not encounter delays in obtaining necessary domestic or foreign regulatory approvals, if at all, or failures to comply with applicable regulatory requirements, or extensive changes in regulation.

We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances.

Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including national collective labor agreements and individual employer labor agreements. These arrangements address a number of specific issues affecting our working conditions including hiring, work time, wages and benefits, and termination of employment. We must make significant payments in order to comply with these requirements.

**Item 2.** ***Properties***

Our corporate headquarters are located in Miami, Florida. Our corporate headquarters share facilities with Diamedix, which owns approximately 56,000 square feet of buildings at its facility in Miami, Florida. From this facility, Diamedix conducts research and development of in vitro diagnostic products, reagent kit manufacturing, marketing, and corporate management activities. Delta leases approximately 25,000 feet of industrial space in Pomezia, Italy. This facility is where the Mago® instrument is manufactured. ImmunoVision leases approximately 5,700 square feet of commercial space in Springdale, Arkansas.

We believe our facilities are in satisfactory condition, are suitable for their intended use and, in the aggregate, have capacities in excess of those necessary to meet our present needs. A portion of our facilities, as well as our corporate headquarters and other critical business functions are located in areas subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major windstorm.

**Item 3.** ***Legal Proceedings***

On March 2, 2001, b2bstores received notice that a shareholder of b2bstores filed a lawsuit against b2bstores and two of its directors in the United States District Court for the Western District of Texas, San Antonio Division. The lawsuit alleges that b2bstores violated certain aspects of Section 14(a) of the Securities Exchange Act of 1934, as amended, and that certain directors breached their fiduciary duties in connection with the merger. The suit seeks the court's determination of declaratory relief as to whether (i) the proxy statement materials sent to shareholders should be considered null, void and unenforceable, (ii) the merger, if accomplished based on the use of the proxy materials, should be set aside, and (iii) the termination fee of $1.0 million, as defined in the merger agreement, should be found void. Our directors and officers deny the allegations and intend to vigorously defend such claims, but the ultimate outcome of any such legal proceeding cannot be determined.

We are also involved in various legal claims and actions and regulatory matters and other notices and demand proceedings arising in the ordinary course of business. While it is not feasible to predict or determine the outcome of these proceedings, in the opinion of management, based on a review with legal counsel, any losses resulting from such legal proceedings would not have a material adverse impact on our financial position, results of operations or cash flows.

**Item 4.** ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the quarter ended December 31, 2001.

## PART II

### Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters*

Since March 15, 2001, following consummation of the merger, our common stock has been listed on the American Stock Exchange and has been traded under the symbol IVD. From February 16, 2000 through March 14, 2001, prior to consummation of the merger, our common stock was listed on the NASDAQ Small Cap Market and was traded under the symbol BTBC.

As of the close of business on March 20, 2002, there were approximately 41 holders of record of our common stock.

The following table sets forth the high and low sales price of a share of our common stock for each quarter in 2001, since March 15, 2001, as reported by the American Stock Exchange and the high and low bids of a share of our common stock for each quarter in 2000 and 2001, from February 16, 2000 through March 14, 2001, as reported by the NASDAQ Small Cap Market:

| 2001 | High | Low |
|---|---|---|
| Fourth Quarter | 4.27 | 2.80 |
| Third Quarter | 5.25 | 2.10 |
| Second Quarter | 5.50 | 2.90 |
| First Quarter (Since March 15, 2001) | 4.80 | 2.80 |
| First Quarter (Through March 14, 2001) | 3.6312 | 1.5000 |
| **2000** | | |
| Fourth Quarter | 2.0312 | 1.1875 |
| Third Quarter | 2.8125 | 1.1250 |
| Second Quarter | 10.0000 | 2.3125 |
| First Quarter (Beginning February 16, 2000) | 19.5000 | 7.3750 |

We did not pay cash dividends on our common stock during 2000 or 2001 and we do not intend to pay any cash dividends in the foreseeable future.

### Item 6. *Selected Financial Data*

The historical selected financial data prior to consummation of the merger are those of the pre-merger Diagnostics with retroactive restatement of equity and earnings per share.

| | For the Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| | (In thousands except per share data) | | | | |
| **Consolidated Income Statement of Operations Data:** | | | | | |
| Net Revenues | $10,299 | $11,793 | $11,237 | $ 9,719 | $ 9,429 |
| Income (loss) from operations | $(3,874) | $ 162 | $(1,441) | $(3,502) | $(5,248) |
| Net loss | $(3,509) | $(1,855) | $(2,466) | $(3,582) | $(4,862) |
| Net loss per common share | $ (.13) | $ (.09) | $ (.12) | $ (.18) | $ (.24) |
| Weighted average number of common shares outstanding | 26,879 | 20,000 | 20,000 | 20,000 | 20,000 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| **Balance Sheet Data:** | | | | | |
| Working capital | $27,812 | $ 6,029 | $ 8,600 | $ 8,176 | $ 7,438 |
| Total assets | $40,147 | $19,113 | $21,662 | $22,120 | $21,264 |
| Total liabilities | $ 3,347 | $11,894 | $12,000 | $ 8,668 | $ 5,404 |
| Total stockholders' equity | $36,800 | $ 7,219 | $ 9,662 | $13,452 | $15,860 |

## Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements and the related Notes to Consolidated Financial Statements on pages 21 to 45 of this Annual Report on Form 10-K.

### Overview

We are the parent corporation of the following three subsidiaries:

- Delta Biologicals, S.r.l.;
- Diamedix Corporation; and
- ImmunoVision, Inc.

Through these subsidiaries, we develop, manufacture, and market diagnostic test kits, or assays, that are used to aid in the detection of disease markers primarily in the areas of autoimmune and infectious diseases. In addition to diagnostic kits, we also design and manufacture laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. We also develop, manufacture, and market raw materials, such as antigens used in the production of diagnostic kits.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy.

From its facility located in Pomezia, Italy, Delta develops and manufactures scientific and laboratory instruments, including its proprietary Mago® instrument, which includes hardware, reagents, and software. The Mago® system, in association with 74 specific assays acquired from Diamedix and third parties, is sold directly in Italy through Delta's independent sales representatives, most of whom work exclusively for Delta. Delta also sells in Italy other diagnostic products manufactured by third parties. Approximately 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are private laboratories. Thus, sales in Italy are heavily concentrated in the public sector.

Diamedix' products are sold in the United States through Diamedix' sale force. Diamedix manufactures 42 assays that the FDA has cleared and that are available to be run in conjunction with the Mago® system. These assays are sold under the trade name immunosimplicity®.

ImmunoVision develops, manufactures, and markets autoimmune reagents and research products for use by clinics, hospitals, research laboratories, and commercial diagnostic manufacturers. These manufacturers (including Diamedix) use these antigens to produce autoimmune diagnostic kits.

On March 21, 2002, we announced that we had signed a non-binding letter of intent with Sigma Diagnostics pursuant to which we would acquire Sigma Diagnostics' global enzyme immunoassay product line. The terms of the transaction are being negotiated and there can be no assurance that the transaction will be consummated or that we will be able to successfully integrate the acquired product line. Under previous agreements with Sigma Diagnostics, which are described above, we sold enzyme immunoassay instrumentation and reagents to Sigma Diagnostics which they marketed throughout the world. If the proposed acquisition is consummated, then we will no longer sell reagents or instrumentation to Sigma Diagnostics, which had been our largest customer for the past three years. Instead, we would sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' enzyme immunoassay customer base. If the proposed acquisition is consummated, our previous agreements with Sigma Diagnostics would cease and any issues relating to the relationship of the parties would be resolved. In the event the proposed acquisition is not consummated and Sigma Diagnostics does not fulfill its

obligations under its agreements with us, we will review our agreements with Sigma Diagnostics to determine what remedies, if any, we may have. In the event the proposed acquisition is not consummated, there can be no assurance that we will be able to replace our largest customer or that any remedies will be available to us in connection with our agreements with Sigma Diagnostics. Any failure to do so or lack of such remedies would have material adverse effect on our business, prospects, operating results, and financial condition.

The historical financial statements prior to the merger of us and the pre-merger Diagnostics are those of the pre-merger Diagnostics with no adjustments except for retroactive restatement, as if a stock split occurred, to reflect the 20,000,000 shares of common stock that IVAX received in the merger as outstanding for all periods presented.

**Results of Operations**

**Year Ended December 31, 2001 Compared to the Year Ended December 31, 2000**

**Net Revenues and Gross Profit**

Net revenue for the year ended December 31, 2001 totaled $10,299,000, a decrease of $1,494,000, or 12.7%, from the $11,793,000 reported in the prior year comparable period. This decrease was comprised of a decrease of $1,965,000 in external net revenue from Italian operations partially offset by an increase in external net revenue of $471,000 from domestic operations. External net revenue from Italian operations totaled $5,683,000 for the year ended December 31, 2001, compared to $7,648,000 for the year ended December 31, 2000. This 25.7% decrease was primarily attributable to decreased sales volume of instrumentation products primarily due to Sigma Diagnostics related issues discussed in Notes 4 and 13. External domestic operations generated net revenue of $4,616,000 for the year ended December 31, 2001, compared to $4,145,000 for the year ended December 31, 2000. This $471,000, or 11.4 % increase, was primarily due to volume increases in revenue from instrumentation placements partially offset by decreased volume of raw material antigen sales. Gross profit for the year ended December 31, 2001 decreased $968,000, or 15.1%, to $5,445,000 (52.9% of net revenue) from $6,413,000 (54.4% of net revenue) for the year ended December 31, 2000. This decrease in gross profit was primarily attributable to decreased revenue from sales of instrumentation products. The decrease in gross profit as a percentage of net revenue of 1.5% was primarily due to lower revenue from sales of instrumentation products (which are generally sold at a higher gross margin) partially offset by improved manufacturing efficiencies achieved due to volume increases in revenue from domestic instrument placements.

**Operating Expenses**

Selling expenses of $3,191,000 (31.0% of net revenue) for the year ended December 31, 2001 were composed of domestic expenses of $1,772,000 and $1,419,000 from Italian operations. For the year ended December 31, 2000, domestic selling expenses were $1,189,000 while $1,435,000 was incurred in Italy, totaling $2,624,000 (22.3% of net revenue). This increase in consolidated selling expenses of $567,000 was primarily due to greater payroll costs related to increased domestic instrument system sales efforts. General and administrative expenses totaled $4,455,000 (43.3% of net revenue) for the year ended December 31, 2001, an increase of $2,373,000, from $2,082,000 (17.7% of net revenue) for the year ended December 31, 2000. This increase was primarily the result of the recognition, in accordance with Accounting Principles Board Opinion No. 25, of $1,486,000 in stock option compensation expense from the conversion of outstanding options under our 1999 Stock Option Plan to non-qualified stock options as a result of the merger. The remaining $892,000 non-cash compensation cost resulting from such conversion will be expensed over the remaining vesting term of the options through June 30, 2003. This increase over the prior period was also due to a partial reimbursement of legal fees received from a settlement of patent litigation in 2000, as well as an increase in professional fees incurred in 2001 associated with the completion of the merger and the establishment of our independent public structure. Research and development expenses totaled $1,418,000 for the year ended December 31, 2001 compared to $1,291,000 for the year ended December 31, 2000, representing 13.8% and 10.9% of net revenues, respectively. The increase of $127,000 was the result of an increase in research and development expenses in the

Italian operations to $257,000 in the year ended December 31, 2001 from $134,000 in the year ended December 31, 2000. This increase was the result of increased research of instrumentation products. The future level of research and development expenditures will depend on, among other things, the outcome of ongoing testing of products and instrumentation under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity.

**Operating Income**

Operating loss was $3,874,000 for the year ended December 31, 2001 compared to operating income of $162,000 in the year ended December 31, 2000. Exclusive of intersegment elimination adjustments that reduced consolidated operating loss by $125,000, operating loss in the year ended December 31, 2001 was composed of an operating loss of $4,417,000 for domestic operations and operating income of $667,000 from Italian operations. Excluding intersegment elimination adjustments that increased consolidated operating income by $24,000 in the year ended December 31, 2000, domestic operations incurred an operating loss of $2,354,000 while Italian operations generated operating income of $2,492,000.

**Other Income (Expense)**

Interest income increased to $743,000 for the year ended December 31, 2001 from $158,000 for the year ended December 31, 2000 due to interest earned on cash received in the merger. Interest expense-related party amounted to $93,000 for the year ended December 31, 2001 and $526,000 for the year ended December 31, 2000, a decrease of $433,000. The related party interest expense was incurred on intercompany advances from IVAX. As a result of the merger, intercompany advances from IVAX were contributed to capital. Other income, net, totaled $58,000 during the year ended December 31, 2001, compared to other expense, net, of $117,000 during the year ended December 31, 2000, an increase of $175,000. This increase was due to larger net foreign currency losses recognized in 2000 by the pre-merger Diagnostics on transactions by its Italian subsidiary, which were denominated in currencies other than its functional currency.

**Year Ended December 31, 2000 Compared to the Year Ended December 31, 1999**

**Net Revenues and Gross Profit**

Net revenues for the year ended December 31, 2000 totaled $11,793,000, an increase of $556,000, or 4.9%, from the $11,237,000 reported in the prior year. This increase was comprised of an increase of $362,000 in net revenues from Italian operations as well as an increase of $194,000 in net revenues from domestic operations. Net revenues from Italian operations totaled $7,648,000 for the year ended December 31, 2000, compared to $7,286,000 for the year ended December 31, 1999. This $362,000, or 3.2%, increase was primarily attributable to increased sales volume of instrumentation, partially offset by the effect of foreign exchange differences. Domestic operations generated net revenues of $4,145,000 for the year ended December 31, 2000, compared to $3,951,000 for the year ended December 31, 1999. This $194,000, or 4.9%, increase was primarily due to volume increases in instrumentation revenue. Gross profit for the year ended December 31, 2000 increased $501,000, or 8.5%, to $6,413,000 (54.4% of net revenues) from $5,912,000 (52.6% of net revenues) for the year ended December 31, 1999. The increase in gross profit and gross profit percentage was primarily attributable to the increase in sales of instrumentation products (which were generally sold at a higher gross margin).

**Operating Expenses**

Selling expenses of $2,624,000 (22.3% of net revenues) for the year ended December 31, 2000 were composed of domestic expenses of $1,189,000 and $1,435,000 from Italian operations. For the year ended December 31, 1999, domestic selling expenses were $1,423,000 while $1,519,000 was incurred in Italy, totaling $2,942,000 (26.2% of net revenues). This decrease was primarily due to the effect of foreign exchange rate differences as well as reductions in payroll and travel costs within the domestic region. General and administrative expenses totaled $2,082,000 (17.7% of net revenues) in the year ended December 31, 2000, a

decrease of $856,000, or 29.1%, from $2,938,000 (26.1% of net revenues) in the year ended December 31, 1999. This decrease was primarily the result of a partial reimbursement of legal fees received from a settlement of patent litigation in 2000, as well as a reduction of legal fees incurred in 1999 associated with patent litigation and accounts receivable collection costs. Research and development expenses of $1,291,000 (10.9% of net revenues) for the year ended December 31, 2000 were composed of domestic expenses of $1,157,000 and $134,000 from Italian operations. For the year ended December 31, 1999, research and development expenses of $1,184,000 from domestic operations and $32,000 from Italian operations totaled $1,216,000 (10.8% of net revenues). The increase of $75,000, or 6.2% was primarily due to increased instrumentation research.

**Operating Income**

Operating income was $162,000 for the year ended December 31, 2000 compared to an operating loss of $1,441,000 in the year ended December 31, 1999. Exclusive of intersegment elimination adjustments that increased consolidated operating loss by $24,000, operating loss in the year ended December 31, 2000 was composed of an operating loss of $2,354,000 for domestic operations and operating income of $2,492,000 from Italian operations. After excluding intersegment elimination adjustments that reduced consolidated operating income by $55,000 in the year ended December 31, 1999, domestic operations incurred an operating loss of $3,194,000 while Italian operations generated operating income of $1,808,000.

**Other Income (Expense)**

Interest income decreased $162,000 to $158,000 for the year ended December 31, 2000 compared to $320,000 for the year ended December 31, 1999. The decrease is due to interest received in 1999 as a result of accounts receivable collection efforts in Italy. Interest expense-related party amounted to $526,000 for the year ended December 31, 2000 and $507,000 for the year ended December 31, 1999, an increase of $19,000. The related party interest was incurred on intercompany advances from IVAX. Other expense, net, totaled $117,000 during the year ended December 31, 2000, compared to other income, net, of $23,000 during the year ended December 31, 1999, a decrease of $140,000. The decrease was due to larger net foreign currency losses recognized in 2000 by the pre-merger Diagnostics on transactions by its Italian subsidiary, which were denominated in currencies other than its functional currency.

**Liquidity And Capital Resources**

At December 31, 2001, our working capital was $27,812,000 compared to $6,029,000 at December 31, 2000. Our net assets on the date of merger were $22,255,000, consisting primarily of cash of $22,285,000. As a condition of the merger, intercompany indebtedness of $9,581,000 existing between IVAX and the pre-merger Diagnostics was contributed to capital. Cash and cash equivalents totaled $23,282,000 at December 31, 2001, as compared to $1,263,000 at December 31, 2000. Substantially all cash and cash equivalents are presently held at one national securities brokerage firm. Accordingly, we are subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver our securities or if the brokerage firm should become bankrupt or otherwise insolvent. We only invest in select money market instruments, municipal securities and corporate issuers.

Net cash flows of $936,000 were used in operating activities during the year ended December 31, 2001, compared to $1,228,000 used during the year ended December 31, 2000. The reduction in cash used during the year ended December 31, 2001 in operating activities compared to the same period of the prior year was primarily the result of an increase in cash received from accounts receivable collections, partially offset by reduced operating results adjusted for non-cash items and an increase in cash utilized to pay accounts payable and accrued expenses.

Net cash flows of $834,000 were used in investing activities during the year ended December 31, 2001, as compared to $517,000 used during the same period of the prior year. The increase in cash used was primarily the result of the acquisition of equipment on lease.

Net cash flows of $24,108,000 were provided by financing activities during the year ended December 31, 2001, compared to $703,000 used during the same period of 2000. The increase in cash provided in 2001 was primarily due to cash of $22,285,000 that was included in our net assets acquired in the merger with the pre-merger Diagnostics. Other differences in net cash flows provided by or used in financing activities during the two year period ending December 31, 2001 are primarily due to funds received or paid to IVAX during the respective years.

Our product research and development expenditures are expected to be approximately $1,600,000 during 2002, subject to adjustment in the event our proposed transaction with Sigma Diagnostics is consummated, although actual expenditures will depend on, among other things, the outcome of clinical testing of products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity. There can be no assurance that we will successfully complete products under development, that we will be able to obtain regulatory approval for any such products, or that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed. In addition, we expect to spend approximately $300,000 in fiscal 2002 to improve and expand our equipment and facilities, subject to adjustment in the event our proposed transaction with Sigma Diagnostics is consummated.

Our principal source of short term liquidity is existing cash and cash equivalents received as a result of the completion of the merger, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over the short term. For the long term, we intend to utilize principally existing cash and cash equivalents as well as internally generated funds, which are anticipated to be derived primarily from the sale of existing diagnostic and instrumentation products and diagnostic and instrumentation products currently under development. To the extent that the aforementioned sources of liquidity are insufficient, we may consider issuing debt or equity securities or curtailing or reducing our operations.

In April 1999, we entered into a three year contract with Sigma Diagnostics, pursuant to which Sigma Diagnostics agreed to purchase from us a minimum number of scientific instruments per year. Twice during the year 2000, Sigma Diagnostics notified us that it desired to suspend shipments of instruments while our representatives and Sigma Diagnostics' representatives resolved certain product issues. The first suspension lasted for a period of approximately four months. The second suspension began in October 2000 and ended in January 2001. During the last six months of 2001 and to date in 2002, Sigma Diagnostics made no purchases of instruments based upon its determination that it had an adequate level of instruments in inventory. In addition, in October 2000, we entered into a three year contract with Sigma Diagnostics pursuant to which we agreed to sell to Sigma Diagnostics certain infectious disease diagnostic kits under a private-label arrangement. Sigma Diagnostics is not required to make a minimum level of purchases under this private-label arrangement. During the years ended December 31, 2001, 2000 and 1999, our net revenues from such sales of instruments, replacement parts and diagnostic kits represented 24.9%, 40.1% and 27.8%, respectively, of our total net revenues for such periods.

On March 21, 2002, we announced that we had signed a non-binding letter of intent with Sigma Diagnostics pursuant to which we would acquire Sigma Diagnostics' global enzyme immunoassay product line. The terms of the transaction are being negotiated. Under previous agreements with Sigma Diagnostics, which are described above, we sold enzyme immunoassay instrumentation and reagents to Sigma Diagnostics which they marketed throughout the world. If the proposed acquisition is consummated, then we will no longer sell reagents or instrumentation to Sigma Diagnostics, which had been our largest customer for the past three years. Instead, we would sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' enzyme immunoassay customer base. There can be no assurance that this acquisition will be successfully consummated or that we will be able to successfully integrate the acquired product line. If the proposed acquisition is consummated, our previous agreements with Sigma Diagnostics would cease and any issues relating to the relationship of the parties would be resolved. In the event the proposed acquisition is not consummated and Sigma Diagnostics does not fulfill its obligations under its agreements with us, we will review our agreements

with Sigma Diagnostics to determine what remedies, if any, we may have. In the event the proposed acquisition is not consummated, there can be no assurance that we will be able to replace our largest customer or that any remedies will be available to us in connection with our agreements with Sigma Diagnostics. Any failure to do so or lack of such remedies would have a material adverse effect on our business, prospects, operating results, and financial condition.

**Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to product returns, allowance for doubtful accounts, inventories, intangible assets, income and other tax accruals, warranty obligations, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our assumptions and estimates may, however, prove to have been incorrect and our actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies and the judgments and estimates we make concerning their application have significant impact on our consolidated financial statements.

A principal source of revenue is our "reagent rental" program in which customers make reagent kit purchase commitments with us that typically last for a period of three to five years. In exchange, we provide at no cost a Mago® instrument and any required instrument service, which are paid for by the customer through these reagent kit purchases over the life of the commitment. We recognize revenue from the reagent kit sales only at the time of shipment and passage of title. Should actual reagent kit or instrument failure rates significantly increase, our future operating results could be negatively impacted by increased warranty obligations and service delivery costs.

We maintain allowances for doubtful accounts, particularly in Italy for the operations of our Italian subsidiary, for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, then we may be required to make additional allowances which would adversely affect our operating results during the period in which the determination or reserve is or was made.

We regularly review inventory quantities on hand and, if necessary, record a provision for excess and obsolete inventory based primarily on our estimates of product demand and production requirements. These estimates of future product demand may prove to be inaccurate, in which case any resulting adjustments to the value of inventory would be recognized in our cost of goods sold at the time of such determination.

Pursuant to SFAS No. 142, "Goodwill and Other Intangible Assets," we will be required to analyze our goodwill for impairment issues during the first six months of fiscal 2002, and on a periodic basis thereafter. In assessing the recoverability of our goodwill and other intangibles, we must make assumptions regarding estimated future cash flows, including current and projected levels of income, business trends, prospects and market conditions, to determine the fair value of the respected assets. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets not previously recorded. Any resulting impairment loss would be recorded as a charge against our earnings and could have a material adverse impact of our financial condition and results of operations.

We accounted for income taxes on our consolidated financial statements on a stand-alone basis as if we had filed our own income tax returns. However, the pre-merger Diagnostics reported its income taxes until the

merger as part of a consolidated group. Therefore, all domestic net operating losses generated prior to the merger were utilized by IVAX. Since the merger, we have experienced domestic losses from operations. Accounting principles generally accepted in the United States require that we record a valuation allowance against the deferred tax asset associated with these losses if it is "more likely than not" that we will not be able to utilize the net operating loss to offset future taxes. Due to the losses from the operations of our domestic operations since the merger, we have provided full valuation reserves against domestic deferred tax assets and currently provide for only foreign income taxes. Over time we may reach levels of profitability which could cause our management to conclude that it is more likely than not that we will realize all or a portion of the net operating loss carryforward. Upon reaching such a conclusion, and upon such time as we reversed the entire valuation against the deferred tax asset, we would then provide for income taxes at a rate equal to our combined federal and state effective rates. This and subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

The critical accounting policies discussed are not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result.

**Recently Issued Accounting Standards**

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin, or SAB, No. 101 regarding revenue recognition. SAB No. 101 clarifies issues relating to revenue recognition in financial statements including income statement presentation and disclosure. SAB No. 101 is effective for us for the fourth fiscal quarter of all years beginning after December 15, 1999. The pre-merger Diagnostics adopted SAB No. 101 on October 1, 2000. The adoption did not have a material effect on our financial position or results of operations.

Effective January 1, 2001, the pre-merger Diagnostics adopted Statement of Financial Accounting Standards, or SFAS, No. 133, Accounting for Derivative Instruments and Hedging Activities, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. All derivatives, whether designated in hedging relationships or not, are required to be recorded on the balance sheet at fair value. If the derivative is designated as a fair value hedge, then the changes in the fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as a cash flow hedge, then the effective portions of changes in the fair value of the derivative are recorded in other comprehensive income and are recognized in the statement of operations when the hedged item affects earnings. Ineffective portions of changes in the fair value of cash flow hedges are recognized in earnings. The adoption of SFAS No. 133 did not have an impact on our financial position or results of operations as we had no derivative financial instruments during the year ended December 31, 2001.

Emerging Issues Task Force, or EITF, Issue No. 00-10, "Accounting for Shipping and Handling Fees and Costs," requires that amounts billed to a customer related to shipping and handling be classified as revenue, and allows companies to adopt a policy of including shipping and handling costs in cost of sales or another statement of operations line item. The pre-merger Diagnostics adopted EITF Issue No. 00-10 in the fourth quarter of 2000 and elected to report the costs of shipping and handling in cost of sales. We have retroactively restated prior quarter and annual amounts to conform to the current classification resulting in an approximately 1% decrease in gross profit margins from those previously reported.

Effective July 1, 2001, we adopted SFAS 141, Business Combinations, which addresses the financial accounting and reporting for business combinations. It supersedes Accounting Principles Board, or APB, Opinion No. 16, Business Combinations, and SFAS 38, Accounting for Pre-acquisition Contingencies of Purchased Enterprises. All business combinations under the scope of this statement must be accounted for using

the purchase method of accounting. This statement applies to all business combinations initiated after June 30, 2001. Our management believes that the adoption of SFAS 141 did not have a material impact on our financial condition or statement of operations.

SFAS 142, Goodwill and Other Intangible Assets, addresses financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, Intangible Assets. It addresses accounting for intangible assets that are acquired individually or with a group of other assets (other than a business combination) upon acquisition. It also addresses accounting for goodwill and other intangible assets after they have been initially recognized in the financial statements. Intangible assets that have indefinite lives and goodwill will no longer be amortized, but rather they must be tested at least annually for impairment using fair values. Intangible assets that have finite useful lives will be amortized over their useful lives. SFAS 142 is effective in fiscal years beginning after December 15, 2001. However, goodwill and intangible assets acquired after June 30, 2001 will be subject immediately to the non-amortization and amortization provisions of SFAS 142. On January 1, 2002 amortization of goodwill acquired prior to June 30, 2001 will cease. This will increase net income by approximately $255,000 per year. However, our management is unable to estimate the extent of impairment, if any, of intangible assets with indefinite lives and goodwill, that may need to be recorded in 2002 or future years.

SFAS 143, Accounting for Asset Retirement Obligations, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal operation of a long-lived asset, except for certain obligations of lessees. It requires that the fair value of an asset retirement obligation be recognized as a liability in the period in which it is incurred if a reasonable estimate can be made and that the associated retirement costs be capitalized as part of the carrying amount of the long-lived asset. SFAS 143 is effective for fiscal years beginning after June 15, 2002. Our management believes that the impact of adoption of this statement will not have a material impact on the Company's consolidated financial statements.

SFAS 144, Accounting for the Impairment or Disposal of Long-lived Assets, addresses financial accounting and reporting for the impairment or disposal of long-lived assets. It supersedes SFAS 121, Accounting for the Impairment of Long Lived Assets and for Long Lived Assets to be Disposed of, and certain provisions of APB Opinion No. 30, Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. It also amends ARB No. 51, Consolidated Financial Statements. SFAS 144 establishes a single accounting model for the accounting for a segment of a business accounted for as a discontinued operation that was not addressed by SFAS 121 and resolves other implementation issues related to SFAS 121. It is effective for fiscal periods beginning after December 15, 2001. Our management believes that the impact of adoption of this statement will not be have a material impact on the Company's consolidated financial statements.

EITF Issue No. 00-14, "Accounting for Certain Sales Incentives," addresses the recognition, measurement and income statement classification for sales incentives offered voluntarily by a vendor, without charge to the customer, in a single exchange transaction at the point of sale. In addition to providing guidance on when to recognize and how to measure the cost of sales incentives, EITF Issue No. 00-14 requires that incentives in the form of a reduction in or refund of the selling price of a product or service be classified as a reduction of revenue. EITF Issue No. 00-14 also requires that incentives in the form of free products or services delivered at the time of sale should be classified as an expense. The amended effective date of adoption is the later of fiscal quarters beginning after March 15, 2001 or fiscal years beginning after December 15, 1999. The pre-merger Diagnostics elected to adopt EITF Issue No. 00-14 in the fourth quarter of 2000. The adoption of EITF Issue No. 00-14 did not have a material impact on our consolidated financial statements.

**Currency Fluctuations**

For the years ended December 31, 2001, 2000 and 1999, approximately 36.1%, 29.6% and 39.1%, respectively, of our net revenues were generated in currencies other than the United States dollar. Fluctuations in

the value of foreign currencies relative to the United States dollar affect our reported results of operations. If the United States dollar weakens relative to the foreign currency, then our earnings generated in the foreign currency will, in effect, increase when converted into United States dollars and vice versa. Exchange rate differences resulting from the strength of the United States dollar against the euro and the Italian lira resulted in a decline of approximately $206,000 in net revenues for the year ended December 31, 2001 compared to the same period of the prior year and a decline of $1,031,000 for the year ended December 31, 2000 compared to the year ended December 31, 1999. During the three years ended December 31, 2001, none of our subsidiaries were domiciled in highly inflationary environments. The effects of inflation on consolidated net revenues and operating income were not significant.

For the year ended December 31, 2001, Delta represented 55.2% of our net revenues. Conducting an international business inherently involves a number of difficulties, risks, and uncertainties, such as export and trade restrictions, inconsistent and changing regulatory requirements, tariffs and other trade barriers, cultural issues, longer payment cycles, problems in collecting accounts receivable, political instability, local economic downturns, seasonal reductions in business activity in Europe during the traditional summer vacation months, and potentially adverse tax consequences.

On January 1, 1999, members of the European Union, including Italy, introduced a single currency, the euro. During the transition period which ended January 1, 2002, European Monetary Union, or EMU, countries had the option of settling transactions in local currencies or in the euro. We have completed our conversion to the euro. The conversion to the euro has resulted in increased costs to us related to updating operating systems, reviewing the effect of the euro on our contracts and updating catalogues and sales materials for our products. The adoption of the euro will limit the ability of an individual EMU country to manage fluctuations in the business cycles through monetary policy.

**Income Taxes**

We recognized a tax provision of $343,000, $1,531,000 and $861,000 for the three years ended December 31, 2001, 2000 and 1999, respectively, which related to foreign operations. Through March 14, 2001, we reported our domestic income taxes as part of a consolidated group with IVAX. All domestic taxable losses generated prior to that date were utilized by IVAX. Effective March 14, 2001, as a result of the merger, we are no longer included in the consolidated income tax returns of IVAX.

For financial statement purposes, we accounted for income taxes on a stand-alone basis as though we had filed our own income tax returns. Our income tax provisions for the years ended December 31, 2001, 2000 and 1999 were different from the amount computed on the loss before provision for income taxes at the United States federal statutory rate of 35% primarily due to non-recognition of the benefits of domestic taxable losses discussed above and non-deductible stock option compensation expense of $1,486,000 in 2001.

As of December 31, 2001, we had no net domestic deferred tax asset, as domestic net operating losses generated prior to the merger were utilized by IVAX and a full valuation allowance has been established against domestic deferred tax assets generated subsequent to March 14, 2001. The foreign net deferred tax asset was $625,000 at December 31, 2001 and is included in other current assets in the accompanying consolidated balance sheet. Realization of the net deferred tax asset is dependent upon generating sufficient future foreign taxable income. Although realization is not assured, over time we believe we will reach levels of profitability which will permit the net deferred tax asset to be realized.

**Risk Of Product Liability Claims**

Developing, manufacturing and marketing diagnostic test kits, reagents and instruments subject us to the risk of product liability claims. We believe that we continue to maintain an adequate amount of product liability insurance, but there can be no assurance that our insurance will cover all existing and future claims. There can be

no assurance that claims arising under any pending or future product liability cases, whether or not covered by insurance, will not have a material adverse effect on our business, results of operations or financial condition. Our current products liability insurance is a "claims made" policy.

### Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows. In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

*Foreign Currency Exchange Rate Risk.* We are exposed to exchange rate risk when our Italian subsidiary enters into transactions denominated in currencies other than its functional currency. For additional information about foreign currency exchange rate risk, see "Currency Fluctuations" in our Management's Discussion and Analysis of Financial Condition and Results of Operations.

*Interest Rate Risk.* We do not have debt obligations. We believe that our exposure to market risk relating to interest rate risk is not material.

*Commodity Price Risk.* We do not believe we are subject to any material risk associated with commodity prices.

### Item 8. *Financial Statements and Supplementary Data*

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

## REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

To The Board of Directors and Shareholders of IVAX Diagnostics, Inc.:

We have audited the accompanying consolidated balance sheets of IVAX Diagnostics, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IVAX Diagnostics, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

As explained in Note 2 to the financial statements, IVAX Diagnostics, Inc. and subsidiaries has given retroactive effect to the change in accounting for Emerging Issues Task Force No. 00-10, "Accounting for Shipping and Handling Fees and Costs."

ARTHUR ANDERSEN LLP

Miami, Florida,
March 20, 2002 (except with respect to the matters discussed in the first paragraph of Note 13, as to which the date is March 21, 2002).

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

| | December 31, 2001 | December 31, 2000 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $23,282,155 | $ 1,262,888 |
| Accounts receivable, net of allowance for doubtful accounts of $1,911,395 and $2,202,135, respectively | 3,192,782 | 4,576,916 |
| Inventories | 2,857,289 | 2,693,887 |
| Deferred income taxes | 624,770 | 602,279 |
| Other current assets | 803,723 | 493,764 |
| Total current assets | 30,760,719 | 9,629,734 |
| PROPERTY, PLANT AND EQUIPMENT: | | |
| Land | 352,957 | 352,957 |
| Buildings and improvements | 2,353,953 | 2,257,882 |
| Machinery and equipment | 1,543,339 | 1,486,882 |
| Furniture and fixtures | 1,333,162 | 1,269,508 |
| | 5,583,411 | 5,367,229 |
| Less—Accumulated depreciation | (4,124,709) | (3,828,822) |
| | 1,458,702 | 1,538,407 |
| OTHER ASSETS: | | |
| Goodwill, net | 6,878,199 | 7,106,135 |
| Equipment on lease, net | 856,439 | 614,666 |
| Other | 192,469 | 223,735 |
| | 7,927,107 | 7,944,536 |
| Total assets | $40,146,528 | $19,112,677 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 801,392 | $ 769,192 |
| Accrued expenses | 2,147,559 | 2,831,593 |
| Total current liabilities | 2,948,951 | 3,600,785 |
| DUE TO PRINCIPAL SHAREHOLDER | — | 7,961,669 |
| OTHER LONG-TERM LIABILITIES | 397,674 | 331,633 |
| Total liabilities | 3,346,625 | 11,894,087 |
| COMMITMENTS AND CONTINGENCIES (Notes 4 and 10) | | |
| SHAREHOLDERS' EQUITY: | | |
| Common stock, par value $0.01 per share, authorized 50,000,000 shares, issued and outstanding 28,635,652 in 2001 and 20,000,000 in 2000 | 286,356 | 200,000 |
| Additional paid-in capital | 44,530,462 | 11,258,251 |
| Accumulated deficit | (5,596,778) | (2,087,637) |
| Accumulated other comprehensive loss | (2,420,137) | (2,152,024) |
| Total shareholders' equity | 36,799,903 | 7,218,590 |
| Total liabilities and shareholders' equity | $40,146,528 | $19,112,677 |

The accompanying notes to consolidated financial statements are an integral part of these balance sheets.

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| NET REVENUES | $10,299,245 | $11,793,010 | $11,236,779 |
| COST OF SALES | 4,854,131 | 5,379,668 | 5,324,356 |
| Gross profit | 5,445,114 | 6,413,342 | 5,912,423 |
| OPERATING EXPENSES: | | | |
| Selling | 3,190,580 | 2,623,738 | 2,941,791 |
| General and administrative (See Note 10) | 4,455,040 | 2,081,602 | 2,938,217 |
| Research and development | 1,418,413 | 1,291,042 | 1,216,040 |
| Goodwill amortization | 254,900 | 255,375 | 257,770 |
| Total operating expenses | 9,318,933 | 6,251,757 | 7,353,818 |
| Income (loss) from operations | (3,873,819) | 161,585 | (1,441,395) |
| OTHER INCOME (EXPENSE): | | | |
| Interest income | 743,322 | 157,584 | 320,210 |
| Interest expense—related party | (93,336) | (525,794) | (506,741) |
| Other income (expense), net | 58,065 | (117,407) | 22,938 |
| Total other income (expense) | 708,051 | (485,617) | (163,593) |
| Loss before provision for income taxes | (3,165,768) | (324,032) | (1,604,988) |
| PROVISION FOR INCOME TAXES | 343,373 | 1,531,280 | 861,216 |
| Net loss | $ (3,509,141) | $ (1,855,312) | $ (2,466,204) |
| Basic and diluted net loss per share | $ (.13) | $ (.09) | $ (.12) |
| Basic and diluted weighted average shares outstanding | 26,878,722 | 20,000,000 | 20,000,000 |

The accompanying notes to consolidated financial statements are an integral part of these statements.

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

| | Common Stock | | Additional Paid-in Capital | Retained Earnings (Accumulated Deficit) | Accumulated Other Comprehensive Loss | Total Shareholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| BALANCE, December 31, 1998 | 20,000,000 | $200,000 | $11,258,251 | $ 2,233,879 | $ (240,227) | $13,451,903 |
| Comprehensive loss: | | | | | | |
| Net loss | — | — | — | (2,466,204) | — | (2,466,204) |
| Translation adjustment | — | — | — | — | (1,323,509) | (1,323,509) |
| Comprehensive loss | | | | | | (3,789,713) |
| BALANCE, December 31, 1999 | 20,000,000 | 200,000 | 11,258,251 | (232,325) | (1,563,736) | 9,662,190 |
| Comprehensive loss: | | | | | | |
| Net loss | — | — | — | (1,855,312) | — | (1,855,312) |
| Translation adjustment | — | — | — | — | (588,288) | (588,288) |
| Comprehensive loss | | | | | | (2,443,600) |
| BALANCE, December 31, 2000 | 20,000,000 | 200,000 | 11,258,251 | (2,087,637) | (2,152,024) | 7,218,590 |
| Comprehensive loss: | | | | | | |
| Net loss | — | — | — | (3,509,141) | — | (3,509,141) |
| Translation adjustment | — | — | — | — | (268,113) | (268,113) |
| Comprehensive loss | | | | | | (3,777,254) |
| Issuance of common stock in connection with merger | 8,621,643 | 86,216 | 22,168,891 | — | — | 22,255,107 |
| Forgiveness of debt to principal shareholder | — | — | 9,581,110 | — | — | 9,581,110 |
| Stock-based compensation from conversion of stock options | — | — | 1,486,488 | — | — | 1,486,488 |
| Exercise of stock options | 14,009 | 140 | 35,722 | — | — | 35,862 |
| BALANCE, December 31, 2001 | 28,635,652 | $286,356 | $44,530,462 | $(5,596,778) | $(2,420,137) | $36,799,903 |

The accompanying notes to consolidated financial statements are an integral part of these statements.

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | | |
| Net loss | $(3,509,141) | $(1,855,312) | $(2,466,204) |
| Adjustments to reconcile net loss to net cash used in operating activities— | | | |
| Depreciation and amortization | 951,838 | 1,026,422 | 1,101,442 |
| Provision for losses on accounts receivable | 25,256 | 43,715 | 68,385 |
| Stock option compensation expense | 1,486,488 | — | — |
| Deferred income tax provision | — | 136,298 | 134,997 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 1,136,708 | (601,140) | 783,920 |
| Inventories | (242,661) | (325,663) | (557,040) |
| Income taxes receivable | — | — | 611,647 |
| Other current assets | (337,442) | 57,312 | 10,381 |
| Other assets | 6,107 | 8,605 | (12,676) |
| Accounts payable and accrued expenses | (538,609) | 216,606 | 76,493 |
| Other long-term liabilities | 85,214 | 64,683 | (181,913) |
| Net cash used in operating activities | (936,242) | (1,228,474) | (430,568) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | | |
| Capital expenditures, net | (241,202) | (149,137) | (118,539) |
| Acquisition of equipment on lease | (593,045) | (367,530) | (445,181) |
| Net cash used in investing activities | (834,247) | (516,667) | (563,720) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | | |
| Proceeds from exercise of stock options | 35,862 | — | — |
| Proceeds from sale of common stock | 22,255,107 | — | — |
| Funds received from (paid to) principal shareholder | 1,816,695 | (703,056) | 4,596,714 |
| Net cash provided by (used in) financing activities | 24,107,664 | (703,056) | 4,596,714 |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS | (317,908) | (506,871) | (1,538,412) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 22,019,267 | (2,955,068) | 2,064,014 |
| CASH AND CASH EQUIVALENTS, beginning of year | 1,262,888 | 4,217,956 | 2,153,942 |
| CASH AND CASH EQUIVALENTS, end of year | $23,282,155 | $ 1,262,888 | $ 4,217,956 |
| SUPPLEMENTAL DISCLOSURES: | | | |
| Interest paid | $ — | $ — | $ — |
| Income taxes paid | $ 847,073 | $ 696,200 | $ 204,430 |

The accompanying notes to consolidated financial statements are an integral part of these statements.

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. ORGANIZATION AND OPERATIONS

IVAX Diagnostics, Inc. ("IVAX Diagnostics" or the "Company") is a Delaware corporation and, through its subsidiaries, is engaged in developing, manufacturing and marketing diagnostic test kits, reagents and instruments for use in hospitals, reference laboratories, clinical laboratories, research laboratories, doctors' offices and other commercial companies. The Company's products and instrumentation are sold primarily to customers in the United States and Italy.

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

*Principles Of Consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

*Use Of Estimates*

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The Company's actual results in subsequent periods may differ from the estimates and assumptions used in the preparation of the accompanying consolidated financial statements. Significant estimates and assumptions include the allowance for doubtful accounts, inventory reserves, litigation accruals, product returns, discounts and allowances, warranty accruals, tax accruals, deferred tax asset valuation allowances and the realization of long-lived assets.

*Recently Issued Accounting Standards*

In December 1999, Securities and Exchange Commission Staff Accounting Bulletin ("SAB") No. 101 regarding revenue recognition was issued. SAB No. 101 clarifies issues relating to revenue recognition in financial statements including income statement presentation and disclosure. SAB No. 101 is effective for the Company for the fourth fiscal quarter of all years beginning after December 15, 1999. As such, the Company adopted SAB No. 101 on October 1, 2000. The adoption did not have a material effect on the Company's financial position or results of operations.

Effective January 1, 2001, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 133, Accounting for Derivative Instruments and Hedging Activities, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. All derivatives, whether designated in hedging relationships or not, are required to be recorded on the balance sheet at fair value. If the derivative is designated as a fair value hedge, the changes in the fair value of the derivative and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as a cash flow hedge, the effective portions of changes in the fair value of the derivative are recorded in other comprehensive income and are recognized in the statement of operations when the hedged item affects earnings. Ineffective portions of changes in the fair value of cash flow hedges are recognized in earnings. The adoption of SFAS No. 133 did not have an impact on the Company's financial position or results of operations as the Company had no derivative financial instruments during the year ended December 31, 2001.

Emerging Issues Task Force ("EITF") Issue No. 00-10, "Accounting for Shipping and Handling Fees and Costs," requires that amounts billed to a customer related to shipping and handling be classified as revenue, and allows companies to adopt a policy of including shipping and handling costs in cost of sales or another statement of operations line item. The Company adopted EITF Issue No. 00-10 in the fourth quarter of 2000 and elected to report the costs of shipping and handling in cost of sales. Prior quarter and annual amounts have been retroactively restated to conform to the current classification resulting in an approximately 1% decrease in gross profit margins from those previously reported.

Effective July 1, 2001, IVAX Diagnostics adopted SFAS 141, Business Combinations which addresses the financial accounting and reporting for business combinations. It supersedes Accounting Principles Board ("APB") Opinion No. 16, Business Combinations and SFAS 38, Accounting for Pre-acquisition Contingencies of Purchased Enterprises. All business combinations under the scope of this statement must be accounted for using the purchase method of accounting. This statement applies to all business combinations initiated after June 30, 2001. Management believes that adoption of SFAS 141 did not have a material impact on the Company's financial condition or statement of operations.

SFAS 142, Goodwill and Other Intangible Assets addresses financial accounting and reporting for acquired goodwill and other intangibles assets and supersedes APB Opinion No. 17, Intangible Assets. It addresses accounting for intangible assets that are acquired individually or with a group of other assets (other than a business combination) upon acquisition. It also addresses accounting for goodwill and other intangible assets after they have been initially recognized in the financial statements. Intangible assets that have indefinite lives and goodwill will no longer be amortized, but rather they must be tested at least annually for impairment using fair values. Intangible assets that have finite useful lives will be amortized over their useful lives. The statement is effective in fiscal years beginning after December 15, 2001. However, goodwill and intangible assets acquired after June 30, 2001 will be subject immediately to the non-amortization and amortization provisions of this statement. On January 1, 2002 amortization of goodwill acquired prior to June 30, 2001 will cease. This will increase net income by approximately $255,000 per year. However, management is unable to estimate the extent of impairment, if any, of intangible assets with indefinite lives and goodwill, that may need to be recorded in 2002 or future years.

SFAS 143, Accounting for Asset Retirement Obligations, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal operation of a long-lived asset, except for certain obligations of lessees. It requires that the fair value of an asset retirement obligation be recognized as a liability in the period in which it is incurred if a reasonable estimate can be made and that the associated retirement costs be capitalized as part of the carrying amount of the long-lived asset. It is effective for fiscal years beginning after June 15, 2002. Management believes that the impact of adoption of this statement will not have a material impact on the Company's consolidated financial statements.

SFAS 144, Accounting for the Impairment or Disposal of Long-lived Assets, addresses financial accounting and reporting for the impairment or disposal of long-lived assets. It supersedes SFAS 121, Accounting for the Impairment of Long Lived Assets and for Long Lived Assets to be Disposed of, and certain provisions of APB Opinion No. 30, Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. It also amends ARB No. 51, Consolidated Financial Statements. It establishes a single accounting model for the accounting for a segment of a business accounted for as a discontinued operation that was not addressed by SFAS 121 and resolves other implementation issues related to SFAS 121. It is effective for fiscal periods beginning after December 15, 2001. Management believes that the impact of adoption of this statement will not have a material impact on the Company's consolidated financial statements.

EITF Issue No. 00-14, "Accounting for Certain Sales Incentives," addresses the recognition, measurement and income statement classification for sales incentives offered voluntarily by a vendor, without charge to the customer, in a single exchange transaction at the point of sale. In addition to providing guidance on when to recognize and how to measure the cost of sales incentives, it requires that incentives in the form of a reduction in or refund of the selling price of a product or service be classified as a reduction of revenue. EITF Issue No. 00-14 also requires that incentives in the form of free products or services delivered at the time of sale should be classified as an expense. The amended effective date of adoption is the later of fiscal quarters beginning after March 15, 2001 or fiscal years beginning after December 15, 1999. The Company elected to adopt EITF Issue No. 00-14 in the fourth quarter of 2000. The adoption of EITF Issue No. 00.14 did not have a material impact on the Company's consolidated financial statements.

*Cash And Cash Equivalents*

The Company considers all investments with an original maturity of three months or less as of the date of purchase to be cash equivalents.

*Inventories*

Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, estimated time required to sell such inventory, remaining shelf life and current market conditions. Reserves are provided as appropriate to reduce excess or obsolete inventories to the lower of cost or market. Inventories consist of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| Raw materials | $1,044,346 | $1,228,781 |
| Work-in-process | 478,860 | 309,216 |
| Finished goods | 1,334,083 | 1,155,890 |
| Total | $2,857,289 | $2,693,887 |

*Property, Plant And Equipment*

Property, plant and equipment are carried at cost, less accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful lives of the assets as follows:

| | Years |
|---|---|
| Buildings and improvements | 5-20 |
| Machinery and equipment | 3-10 |
| Furniture and fixtures | 3-10 |

Costs of major additions and improvements are capitalized and expenditures for maintenance and repairs which do not extend the life of the assets are expensed. Upon sale or disposition of property, plant and equipment, the cost and related accumulated depreciation is eliminated from the accounts and any resulting gain or loss is credited or charged to operations.

Depreciation expense related to property, plant and equipment was $317,304, $346,839 and $393,800 for the years ended December 31, 2001, 2000 and 1999, respectively.

*Goodwill, Net*

Cost in excess of net assets of acquired companies (goodwill) is amortized using the straight-line method over 40 years. Goodwill is reported net of accumulated amortization and consists of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| Goodwill | $9,236,929 | $9,219,591 |
| Less—Accumulated amortization | 2,358,730 | 2,113,456 |
| | $6,878,199 | $7,106,135 |

Amortization expense related to goodwill was $254,900, $255,375 and $257,770 for the years ended December 31, 2001, 2000 and 1999, respectively.

*Equipment On Lease, Net*

The cost of the Company's owned instruments, which are placed under reagent rental programs at customer facilities for testing and usage of the Company's products (see Note 2—Revenue Recognition), less accumulated amortization, consists of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| Equipment on lease at cost | $2,759,851 | $2,227,122 |
| Less—Accumulated amortization | 1,903,412 | 1,612,456 |
| | $ 856,439 | $ 614,666 |

Equipment on lease is amortized over three years. Amortization expense related to equipment on lease was $334,754, $396,185 and $427,468 for the years ended December 31, 2001, 2000 and 1999, respectively.

*Review For Impairment*

The Company continually evaluates whether events and circumstances have occurred that indicate that the remaining balance of long-lived assets, including goodwill, may not be recoverable. When factors indicate that goodwill or other long-lived assets may be impaired, the Company uses various methods to estimate future cash flow, including current and projected levels of income, business trends, prospects and market conditions. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, then an impairment loss is recognized based on the excess of the carrying amount over the estimated fair value of the asset. Any impairment amount is charged to operations.

Future events could cause the Company to conclude that impairment indicators exist and that long-lived assets, including goodwill, are impaired. Any resulting impairment loss could have a material adverse impact on our financial condition and results of operations.

*Foreign Currencies*

The Company's operations include a subsidiary that is located in Italy. Assets and liabilities as stated in the local reporting and functional currency are translated at the rate of exchange prevailing at the balance sheet date. The gains or losses that result from this process are shown in the "Accumulated other comprehensive loss" caption in the Shareholders' equity section of the accompanying consolidated balance sheets. Amounts in the consolidated statements of operations are translated at the average rates for the period.

The Company is exposed to the risk of currency fluctuation, as a significant portion of its operations occur in Italy. The Company does not use financial derivatives to hedge either exchange rates or interest rate fluctuations.

*Financial Instruments*

The carrying amounts of cash and cash equivalents, accounts receivable, and accounts payable approximate fair value due to the short-term maturity of the instruments and reserves for potential losses, as applicable. The Company does not speculate in the foreign exchange market.

*Revenue Recognition*

Revenue and the related cost of sales on sales of test kits and instruments are recognized at the time of shipment. Net revenue is comprised of gross revenue less provisions for expected product returns, allowances and discounts. These provisions and discounts totaled $49,540, $14,978 and $34,968 for the years ended December 31, 2001, 2000 and 1999, respectively.

The Company also owns instruments that it places, under reagent rental programs common to the industry, for periods of time at customer facilities for testing and usage with the Company's products ("Equipment on lease"). The instrument system, utilized by customers to expedite the performance of certain tests, is paid for over an agreed upon contract period by the purchase of test kits. Revenue is recognized ratably over the rental period.

Provision for estimated warranty claims are established by the Company concurrently with the recognition of revenue. Provisions are established in accordance with accounting principles generally accepted in the United States based upon consideration of a variety of factors, including actual experience for products during the past several years by product type, the market for the product and projected economic conditions. Actual product returns, allowances and discounts and warranty claims incurred are, however, dependent upon future events. The Company continually monitors the factors that influence product returns, allowances and discounts and warranty claims and makes adjustments to these provisions when management believes that actual amounts may differ from established reserves.

*Research And Development Costs*

Company sponsored research and development costs related to future products are expensed currently.

*Stock-Based Compensation Plans*

The employees of the Company are eligible to participate in the IVAX 1997 Employee Stock Option Plan as well as the Company's stock option plan. As permissible under SFAS No. 123, Accounting for Stock-based Compensation, the Company accounts for all stock-based compensation arrangements using the intrinsic value method prescribed by APB Opinion No. 25, Accounting for Stock Issued to Employees, and discloses pro forma net loss and net loss per share amounts as if the fair value method had been adopted.

*Comprehensive Loss*

Comprehensive loss, consisting of the sum of net loss and translation adjustment, was $3,777,254, $2,443,600 and $3,789,713 for the years ended December 31, 2001, 2000 and 1999, respectively.

*Loss Per Share*

Loss per share is computed by dividing net loss by the weighted average number of common and common equivalent shares outstanding during the period. All outstanding stock options are considered common stock equivalents. The dilutive effect, if any, of those options is calculated using the treasury stock method. Basic and diluted net loss per share are the same for all periods presented. The number of stock options outstanding not included in the calculation of earnings per share because their impact is antidilutive was 2,134,128, 1,108,795, and 1,108,795 for the years ended December 31, 2001, 2000 and 1999, respectively.

*Reclassifications*

Certain reclassifications have been made to prior year consolidated financial statements to conform to the current year presentation.

## 3. MERGER

On March 14, 2001, b2bstores.com, Inc. ("b2bstores.com"), IVAX Corporation ("IVAX" or the "Parent") and IVAX Diagnostics, a wholly-owned subsidiary of IVAX at that date, consummated a merger (the "Merger") of IVAX Diagnostics into b2bstores.com pursuant to which all of the issued and outstanding shares of IVAX Diagnostics were converted into 20,000,000 shares of b2bstores.com stock and b2bstores.com's name was changed to IVAX Diagnostics, Inc. Prior to the Merger, b2bstores.com was an internet business services company that was a non-operating public shell. Net assets of b2bstores.com on the date of Merger were $22,255,107, consisting primarily of cash of $22,285,064. Additionally, as a condition of the Merger, intercompany indebtedness of $9,581,110 existing between IVAX and IVAX Diagnostics was contributed to capital. For accounting purposes, the Merger was accounted for as sale of stock for cash. The historical financial statements prior to the acquisition are those of the former IVAX Diagnostics with retroactive restatement, as if a stock split occurred, to reflect the 20,000,000 shares of b2bstores.com common stock that IVAX received in the merger as outstanding for all periods presented. Following the Merger, IVAX' 20,000,000 shares of IVAX Diagnostics represents approximately 70% of the issued and outstanding shares of IVAX Diagnostics.

As a result of the Merger, all non-qualified stock options previously granted to employees of IVAX Diagnostics under the IVAX Diagnostics, Inc. 1999 Stock Option Plan (Note 8) were converted into non-qualified stock options to purchase 1,108,795 shares of the Company's common stock. As a result of this conversion, a measurement date was triggered under APB Opinion No. 25, Accounting for Stock Issued to Employees, and the total non-cash compensation cost of $2,378,364 was determined. Of this amount, $1,486,488 was recorded in general and administrative expense in the accompanying statement of operations for the year ended December 31, 2001. The remaining cost will be expensed and recognized in additional paid-in capital over the remaining vesting term of the options through June 30, 2003.

## 4. CONCENTRATION OF CREDIT RISK

The Company performs periodic credit evaluations of its customers' financial condition and provides allowances for doubtful accounts as required. One customer (Sigma Diagnostics) accounted for 3.9% and 40.8%

of the Company's net accounts receivable as of December 31, 2001 and 2000, respectively. The same customer accounted for 24.9%, 40.1% and 27.8% of the Company's net revenues for the years ended December 31, 2001, 2000 and 1999, respectively. The customer and the Company entered into a contract in April 1999, pursuant to which, subject to terms of the agreement, the customer agreed to purchase minimum levels of the Company's instrumentation products during the three-year period beginning May 1, 1999. Twice during 2000, the Company's largest customer suspended its purchases of the Company's products for several months while representatives of the Company and the customer resolved certain product issues. On January 10, 2001, shipments to the customer resumed. During the third and fourth quarters of the year ended December 31, 2001 the customer made no purchases of instrumentation products based upon the customer's determination that they had an adequate level of instruments in inventory (See Note 13).

In addition, in October 2000 the customer and the Company entered into a three-year contract pursuant to which the Company agreed to sell to the customer certain diagnostic kits under a private-label arrangement. The customer is not obligated to make a minimum level of purchases under this private-label arrangement.

The Company's accounts receivables are generated from sales made from both the United States and Italy. As of December 31, 2001 and 2000, $2,561,948 and $4,149,874, respectively, of the Company's net accounts receivable were due in Italy. Of the total net accounts receivable, 66.8% at December 31, 2001 and 44.7% at December 31, 2000 were due from hospitals and laboratories controlled by the Italian government.

The allowance for doubtful accounts was $1,911,395, $2,202,135 and $2,361,532 at December 31, 2001, 2000 and 1999, respectively, and activity for the years ended December 31, 2001, 2000 and 1999 was as follows:

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| January 1 balance | $2,202,135 | $2,361,532 | $2,314,713 |
| Provision for doubtful accounts | 25,256 | 43,715 | 68,385 |
| Write-offs | (209,028) | — | (2,032) |
| Effects of changes in foreign exchange rates | (106,968) | (203,112) | (19,534) |
| | $1,911,395 | $2,202,135 | $2,361,532 |

Substantially all cash and cash equivalents are presently held at one national securities brokerage firm. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent. The Company only invests in select money market instruments, municipal securities and corporate issuers.

## 5. INCOME TAXES

The Company reported its income taxes until March 14, 2001 as part of a consolidated group with IVAX. For financial statement purposes, the Company accounts for income taxes on a stand-alone basis as though the Company had filed its own income tax returns.

The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes. Under SFAS No. 109, deferred tax assets or liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability from period to period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, then a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance would be included in the provision for deferred income taxes in the period of change. At December 31, 2001 and 2000, the Company has provided full valuation reserves against its net domestic deferred tax assets because the Company does not believe that it is more likely than not that some portion or all of the deferred tax assets will be realized.

The provision for income taxes consists of the following:

| | December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| Current: | | | |
| Foreign | $343,373 | $1,394,982 | $726,219 |
| Deferred: | | | |
| Foreign | — | 136,298 | 134,997 |
| Total | $343,373 | $1,531,280 | $861,216 |

The significant components of net deferred tax asset balances are as follows:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| Accounts receivable allowances | $ 663,114 | $ 727,822 |
| Reserves and accruals | 358,366 | 441,335 |
| Differences in capitalization of inventory costs | 50,068 | 77,084 |
| Other | (1,377) | — |
| Domestic valuation allowance | (445,401) | (643,962) |
| Deferred income taxes | 624,770 | 602,279 |
| Depreciation and basis differences on fixed assets | 207,572 | 264,865 |
| Goodwill amortization | (241,801) | (204,219) |
| Domestic net operating losses | 1,483,700 | — |
| Other | 1,000 | 1,000 |
| Domestic valuation allowance | (1,450,471) | (2,135) |
| Amount included in "Other assets" | — | 59,511 |
| Net deferred tax asset | $ 624,770 | $ 661,790 |

A reconciliation of the difference between the expected provision for income taxes using the statutory U.S. Federal tax rate and the Company's actual provision is as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| Benefit for income taxes at U.S. Federal statutory rate of 35% | $(1,108,019) | $ (113,411) | $ (561,746) |
| Net impact of non-recognition of domestic losses | 1,338,803 | 907,559 | 1,149,905 |
| Effect of foreign non-deductible expense | — | 700,000 | — |
| Foreign tax rate differential | 112,589 | 37,132 | 273,057 |
| Provision for income taxes | $ 343,373 | $1,531,280 | $ 861,216 |

Domestic losses include both non-deductible stock option compensation expense of $1,486,488 described in Note 3 and non-deductible goodwill amortization of $178,800 in the year ended December 31, 2001, as well as non-deductible goodwill amortization of $178,800 in each of the years ended December 31, 2000 and 1999.

As discussed above, the Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards. Approximately $746,000 of the valuation allowance relates to the tax benefit of stock options exercised which has not yet been credited to additional paid-in capital. The portion of these domestic net operating loss carryforwards generated prior to March 14, 2001 were utilized by IVAX. On a separate return basis, no recognition of that utilization is reflected in the accompanying consolidated financial statements. Net operating losses generated by the Company after March 14, 2001 are approximately $4,010,000 and are available for use prior to their expiration in 2021.

United States income taxes have not been provided on undistributed earnings of foreign subsidiaries, as such earnings are being retained indefinitely by such subsidiaries for reinvestment. The distribution of these earnings would first reduce the domestic valuation allowance before resulting in additional United States income taxes.

## 6. EMPLOYEE BENEFIT PLAN

Prior to March 14, 2001, the Company's employees within the United States were eligible to participate in IVAX' 401(k) Retirement Plan, which permits pre-tax employee payroll contributions (subject to certain limitations) and discretionary employer matching contributions. Total matching contributions for the years ended December 31, 2001, 2000 and 1999 were $79,462, $62,990 and $59,569, respectively. Subsequent to the Merger, the Company established its own 401(k) employee savings plan which also allows for pre-tax employee payroll contributions and discretionary employer matching contributions. No matching contributions have been made into this plan.

## 7. ACCRUED EXPENSES

Accrued expenses consist of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| Payroll costs | $ 447,132 | $ 405,080 |
| Taxes | 1,207,475 | 1,609,973 |
| Professional fees | 201,870 | 454,656 |
| Royalties | 150,000 | 26,000 |
| Other | 141,082 | 335,884 |
| | $2,147,559 | $2,831,593 |

## 8. SHAREHOLDERS' EQUITY

*Common Stock*

Concurrent with the approval of the merger discussed in Note 3, the Company amended its articles of incorporation to increase the number of shares of authorized common stock from 25,000,000 to 50,000,000.

*Pre-Merger Employee Options And Stock Purchase Arrangements*

In connection with the initial public offering of b2bstores.com, the underwriters' representatives were issued warrants that expire in February 2005 to purchase up to 400,000 shares of the Company's common stock at a price of $13.20 per share. As of December 31, 2001, these warrants remain outstanding.

Employees of the Company were eligible to participate in the IVAX 1997 Employee Stock Option Plan, as amended (the "1997 Plan"), which permits the issuance of options to employees and consultants to purchase shares of IVAX common stock. The 1997 Plan provides that the exercise price of the issued options shall be no less than the fair market value of IVAX' common stock on the date of grant and that the option terms shall not exceed ten years. Since the approval of the Company's 1999 Stock Option Plan (discussed below), no option grants have been made to Company employees from this 1997 Plan. As of December 31, 2001, 86,379 options under the 1997 Plan are held by Company employees at prices ranging from $4.44 to $14.63, with 58,254 shares exercisable.

Effective June 29, 1999, the Board of Directors of IVAX Diagnostics approved the Company's 1999 Stock Option Plan (the "1999 Plan"). The 1999 Plan permits the issuance of options to employees, non-employee directors and consultants of the Company to purchase up to 2,000,200 shares of the 50,000,000 authorized shares of common stock of the Company. In June and August of 1999, non-qualified options for 1,144,909 shares of common stock (as determined below) were granted with an exercise price of $.73 per share, a vesting schedule of 50% at the end of year 2 and 25% at the end of years 3 and 4 and expiration dates ranging from June to August of 2006. As of December 31, 2001 options for 1,090,795 shares of common stock were outstanding. No options have been exercised to date under the 1999 Plan.

At the effective time of the merger, automatically and without any action on the part of an option holder, the surviving company assumed each outstanding option granted under the 1999 Plan as an option to purchase shares of the surviving company's common stock under the same terms and conditions as the outstanding option. The number of shares issuable upon the exercise of an option under the 1999 Plan proportionately increased by multiplying the number of outstanding options by the exchange ratio of the merger. The exercise price per share was proportionately decreased by dividing the exercise price by the exchange ratio of the merger. For the year ended December 31, 2001, non-cash compensation was recorded as a result of the conversion of the 1999 Plan into non-qualified stock options to purchase shares of the Company's common stock (See Note 3). For the years ended December 31, 2000 and 1999, no compensation expense was recorded related to the 1999 Plan because there has not been an increase in the book value per share above the $.73 exercise price.

On September 30, 1999 the Board of Directors and stockholders of b2bstores.com approved the 1999 Performance Equity Plan (the "Performance Plan"). The Performance Plan authorizes the grant of up to 2,000,000 shares of common stock to key employees, officers, directors and consultants. Both incentive and non-qualified options may be issued under the Performance Plan. Prior to the creation of the Performance Plan, options to purchase an additional 1,000,000 shares of common stock were granted by the Board of Directors of b2bstores.com to selected former officers of that company. As of December 31, 2001, 758,333 options were outstanding from the original grants at prices ranging from $1.81 to $11.50. Following the merger on March 14, 2001, 14,009 options were exercised under the Performance Plan.

*Post-Merger Stock Option Plans*

As discussed above, effective June 29, 1999, the Board of Directors of IVAX Diagnostics approved the Company's 1999 Plan that permits the issuance of options to employees, non-employee directors and consultants of the Company to purchase up to 2,000,200 shares of the Company's common stock. These options had expiration dates ranging from June to August of 2006. As of December 31, 2001 options for 1,090,795 shares of common stock were outstanding. No options have been exercised to date.

Also discussed above, on September 30, 1999 the Board of Directors and stockholders of b2bstores.com approved the Performance Plan that authorizes the grant of up to 2,000,000 shares of common stock to key employees, officers, directors and consultants. Following the merger on March 14, 2001, 285,000 options granted by the Company were issued under the Performance Plan.

Transactions under the 1999 Plan and Performance Plan for options held by employees of the Company are summarized as follows:

| | Number of Shares | Weighted Average Exercise Price |
|---|---|---|
| Outstanding at January 1, 1999 | — | $ — |
| Granted | 1,144,909 | 0.73 |
| Terminated | — | — |
| Outstanding at December 31, 1999 | 1,144,909 | 0.73 |
| Terminated | (36,114) | 0.73 |
| Outstanding at December 31, 2000 | 1,108,795 | 0.73 |
| Granted | 285,000 | 2.99 |
| Terminated | (18,000) | 0.73 |
| Outstanding at December 31, 2001 | 1,375,795 | 1.19 |
| Options exercisable at December 31, 2001 | 580,398 | $0.86 |

The Company's pro forma net loss and pro forma weighted average fair value of options granted, with related assumptions, assuming the Company had adopted the fair value method of accounting for all stock-based compensation arrangements consistent with the provisions of SFAS No. 123, using the Black-Scholes option pricing model, are indicated below for the years ended December 31, 2001, 2000 and 1999.

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Net loss as reported | $(3,509,141) | $(1,855,312) | $(2,466,204) |
| Pro forma net loss | $(3,758,703) | $(1,913,498) | $(2,524,387) |
| Pro forma basic and diluted | | | |
| Loss per share | (0.14) | (0.10) | (0.13) |
| Pro forma weighted | | | |
| Average fair value of options granted | 1.18 | 0.21 | 0.21 |
| Expected life (years) | 6.8 | 7.0 | 7.0 |
| Risk-free interest rate | 5.0% | 5.0% | 5.0% |
| Expected volatility | 128% | 0% | 0% |
| Dividend yield | — | — | — |

## 9. SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains the Company's subsidiaries in the United States and corporate operations. The Company's other segment—the Italian region—contains the Company's subsidiary located in Italy. The information provided is based on internal reports and was developed and utilized by management for the sole purpose of tracking trends and changes in the results of the regions. The information, including the allocations of expense and overhead, was calculated based on a management approach and may not reflect the actual economic costs, contributions or results of operations of the regions as stand alone businesses. If a different basis of presentation or allocation were utilized, the relative

contributions of the regions might differ but the relative trends would, in management's view, likely not be materially impacted. The table below sets forth net revenue, income from operations and assets by region.

| | Domestic | Italian | Eliminations | Total |
|---|---|---|---|---|
| December 31, 2001: | | | | |
| External net sales | $ 4,615,828 | $ 5,683,417 | $ — | $10,299,245 |
| Intercompany sales | 663,874 | 825,523 | (1,489,397) | — |
| Net revenue | $ 5,279,702 | $ 6,508,940 | $(1,489,397) | $10,299,245 |
| Income (loss) from Operations | $(4,416,825) | $ 667,243 | $ (124,237) | $(3,873,819) |
| Assets | $28,435,144 | $11,896,562 | $ (185,178) | $40,146,528 |
| December 31, 2000: | | | | |
| External net sales | $ 4,144,986 | $ 7,648,024 | $ — | $11,793,010 |
| Intercompany sales | 573,377 | 400,524 | (973,901) | — |
| Net revenue | $ 4,718,363 | $ 8,048,548 | $ (973,901) | $11,793,010 |
| Income (loss) from Operations | $(2,354,438) | $ 2,491,529 | $ 24,494 | $ 161,585 |
| Assets | $ 4,377,560 | $14,766,944 | $ (31,827) | $19,112,677 |
| December 31, 1999: | | | | |
| External net sales | $ 3,950,767 | $ 7,286,012 | $ — | $11,236,779 |
| Intercompany sales | 630,968 | 429,899 | (1,060,867) | — |
| Net revenue | $ 4,581,735 | $ 7,715,911 | $(1,060,867) | $11,236,779 |
| Income (loss) from Operations | $(3,193,725) | $ 1,807,734 | $ (55,404) | $(1,441,395) |
| Assets | $ 4,205,192 | $17,534,366 | $ (77,800) | $21,661,758 |

## 10. COMMITMENTS AND CONTIGENCIES

*Leases*

The Company leases office, plant and warehouse facilities under non-cancellable operating leases. Rent expense for the years ended December 31, 2001, 2000 and 1999 totaled approximately $230,809, $189,395 and $202,459, respectively. The future minimum lease payments under non-cancellable capital leases and their related assets recorded at December 31, 2001 and 2000 were not material. The future minimum lease payments under non-cancellable operating leases with initial or remaining terms of one year or more at December 31, 2001, were as follows:

| | Operating Leases |
|---|---|
| 2002 | $211,931 |
| 2003 | 187,431 |
| 2004 | 78,096 |
| Total minimum lease payments | $477,458 |

*Litigation, Claims And Assessments*

In August of 1996, a company filed a declaratory judgment action seeking to invalidate certain patents licensed from the Company. A settlement was reached in favor of the Company in 2000 for $500,000. This amount was received and recorded by the Company in 2000 as a reduction of general and administrative expenses.

The Company is involved in various legal claims and actions and regulatory matters, and other notices and demand proceedings arising in the ordinary course of business. While it is not feasible to predict or determine the outcome of these proceedings, in the opinion of management, based on a review with legal counsel, any losses resulting from such legal proceedings would not have a material adverse impact on the financial position, results of operations or cash flows of the Company.

On March 2, 2001, b2bstores.com received notice that a shareholder of b2bstores.com filed a lawsuit against b2bstores.com and two of its directors. The lawsuit alleges that b2bstores.com violated certain aspects of Section 14(a) of the Securities Exchange Act of 1934, as amended, and that certain directors breached their fiduciary duties in connection with the Merger. The suit seeks the court's determination of declaratory relief as to whether (i) the proxy statement materials sent to shareholders should be considered null, void and unenforceable, (ii) the Merger, if accomplished based on the use of the proxy materials, should be set aside, and (iii) the termination fee of $1.0 million, as defined in the Merger Agreement, shall be found void. The directors and officers of the Company deny the allegations and intend to vigorously defend such claims, but the ultimate outcome of any such legal proceeding cannot be determined.

## 11. RELATED-PARTY TRANSACTIONS

Included in the accompanying consolidated balance sheets as other assets at December 31, 2001 and as due to principal shareholder at December 31, 2000 are amounts due to (from) IVAX as follows:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| Amounts due to IVAX, unsecured and interest bearing | $ — | $4,144,812 |
| Amounts due to (from) IVAX, unsecured and noninterest bearing | (82,000) | 3,816,857 |
| | $(82,000) | $7,961,669 |

IVAX charged interest, which is included in the accompanying statement of operations, on the interest bearing advances made prior to March 14, 2001 at prime plus 1%, which ranged from 8.0% to 9.5% from 1999 to 2001.

Prior to March 14, 2001, IVAX provided administration and funded health care claims on behalf of the Company and charged the Company a fee reflective of the cost of service. Additionally, IVAX provided certain legal, treasury, tax, insurance, payroll and human resource service to the Company for which no fee was charged to the Company. IVAX is continuing to provide certain services to the Company under a cost-plus service agreement. No material payments were made during the period after March 14, 2001.

## 12. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following tables summarize selected quarterly data of the Company for the years ended December 31, 2001 and 2000 (in thousands except per share data):

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Full Year |
|---|---|---|---|---|---|
| **2001** | | | | | |
| Net revenues | $ 3,287 | $2,850 | $ 1,910 | $ 2,252 | $10,299 |
| Gross profit | 1,886 | 1,586 | 921 | 1,052 | 5,445 |
| Loss from operations | (1,079) | (362) | (1,128) | (1,305) | (3,874) |
| Net loss | (1,320) | (199) | (865) | (1,125) | (3,509) |
| Basic and diluted loss per share | (0.05) | (0.01) | (0.03) | (0.04) | (0.13) |
| **2000** | | | | | |
| Net revenues | $ 3,922 | $2,718 | $ 3,288 | $ 1,865 | $11,793 |
| Gross profit | 2,250 | 1,420 | 1,858 | 885 | 6,413 |
| Loss from operations | 832 | (223) | 335 | (782) | 162 |
| Net loss | 243 | (525) | (131) | (1,442) | (1,855) |
| Basic and diluted loss per share | 0.01 | (0.03) | (0.01) | (0.07) | (.09) |

## 13. SUBSEQUENT EVENT

On March 21, 2002, the Company announced that it had signed a non-binding letter of intent with Sigma Diagnostics, Inc., a wholly-owned subsidiary of Sigma- Aldrich Corporation, pursuant to which the Company would acquire Sigma Diagnostics' global enzyme immunoassay product line. The terms of the transaction are being negotiated and there can be no assurance that the transaction will be consummated or that the Company will be able to successfully integrate the acquired product line. Under previous agreements with Sigma Diagnostics, which are described in Note 4, the Company sold enzyme immunoassay instrumentation and reagents to Sigma Diagnostics which they marketed throughout the world. If the proposed acquisition is consummated, reagents or instrumentation will no longer be sold by the Company to Sigma Diagnostics, which had been the Company's largest customer for the past three years. Instead, the Company would sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' enzyme immunoassay customer base. If the proposed acquisition is consummated, our previous agreements with Sigma Diagnostics would cease and any issues relating to the relationship of the parties would be resolved. In the event the proposed acquisition is not consummated and Sigma Diagnostics does not fulfill its obligations under its agreements with the Company, the Company will review its agreements with Sigma Diagnostics to determine what remedies, if any, the Company may have. In the event the proposed acquisition is not consummated, there can be no assurance that the Company will be able to replace its largest customer or that any remedies will be available to it in connection with its agreements with Sigma Diagnostics. Any failure to do so or lack of such remedies would have a material adverse effect on the Company's business, prospects, operating results, and financial condition.

**Item 9.** ***Changes In and Disagreements With Accountants on Accounting and Financial Disclosure***

Not applicable.

## PART III

**Item 10.** ***Directors and Executive Officers***

The following table sets forth information with respect to our directors and certain of our executive officers as of March 20, 2002.

| Name | Age | Position |
|---|---|---|
| Giorgio D'Urso | 66 | Chief Executive Officer, President and Director |
| Duane M. Steele | 51 | Vice President–Business Development |
| Mark Deutsch | 39 | Chief Financial Officer and Vice President–Finance |
| Phillip Frost, M.D. | 65 | Chairman of the Board |
| Neil Flanzraich | 58 | Director |
| Jane Hsiao, Ph.D. | 54 | Director |
| John Harley, M.D. | 52 | Director |
| Jack Borsting, Ph.D. | 73 | Director |
| Randall K. Davis | 38 | Director |
| Jay Raubvogel | 52 | Director |

Set forth below are of the names, ages, positions held and business experience, including during the past five years, of our directors and certain of our executive officers as of March 20, 2002. Officers serve at the discretion of the board of directors. There is no family relationship between any of the directors or executive officers and there is no arrangement or understanding between any director or executive officer and any other person pursuant to which the director or executive officer was selected.

Mr. Giorgio D'Urso, age 66, has served as our President and Chief Executive Officer and as a director since the merger and had served in the same capacities with the pre-merger Diagnostics since 1996. He has served as President and Chief Executive Officer of Diamedix since 1993, President of Delta since 1980, and President of ImmunoVision since 1995. He has over 33 years of diagnostics industry experience. Mr. D'Urso founded Delta, and was its Managing Director from 1980 to 1998. From 1976 to 1980, Mr. D'Urso founded and served as the General Manager of Menarini Diagnostici, Florence, Italy, a division of Menarini S.A.S. Mr. D'Urso also founded and supervised Menarini Diagnosticos S.A. in Spain. From 1974 to 1976, Mr. D'Urso served as the Marketing Manager of the diagnostic division of SmithKline & French S.P.A. in Milan, Italy. From 1969 to 1974, Mr. D'Urso served as the Marketing Manager of Laboratori Travenol S.P.A. in Rome, Italy.

Mr. Duane M. Steele, age 51, has served as our Vice President–Business Development since the merger and had served in the same capacity with the pre-merger Diagnostics since 1996. He joined Diamedix in 1995 and has over 25 years of diagnostics industry experience. He has served as the Chief Operating Officer of Diamedix since 1997. From 1995 to 1997, he served as Vice President–Business Development of Diamedix. From 1990 to 1994, he served as President and Chief Executive Officer of LaserCharge, Inc. in Austin, Texas. From 1988 to 1989, Mr. Steele was the General Manger of Austin Biological Laboratories, Inc. From 1972 to 1987, Mr. Steele held a variety of positions with Kallestad Diagnostics, Inc., including Senior Vice President.

Mr. Mark Deutsch, age 39, has served as Chief Financial Officer and Vice President–Finance since the merger and had served in the same capacities with the pre-merger Diagnostics since 1996. He has served as the Vice President–Finance of Diamedix since 1993 and has 8 years of diagnostics industry experience. From 1988 to 1993,

Mr. Deutsch held various positions including Accounting Manager of IVAX and Controller of certain subsidiaries of IVAX. From 1985 to 1988, Mr. Deutsch worked for Arthur Andersen & Co. as a Senior Accountant.

Dr. Phillip Frost, age 65, has served as Chairman of the Board of Directors since the merger. He has served as the Chairman of the Board of Directors and Chief Executive Officer of IVAX since 1987. He served as President of IVAX from July 1991 until January 1995. He was the Chairman of the Department of Dermatology at Mt. Sinai Medical Center of Greater Miami, Miami Beach, Florida from 1972 to 1990. Dr. Frost was Chairman of the Board of Directors of Key Pharmaceuticals, Inc. from 1972 to 1986. He is Chairman of the Board of Directors of Whitman Education Group, Inc. (proprietary education), a director of Northrop Grumman Corp. (aerospace), and a director of Ladenburg Thalmann Financial Services Inc. (financial services). He is Chairman of the Board of Trustees of the University of Miami and a member of the Board of Governors of the American Stock Exchange. Dr. Frost is also a director of the Center for Blood Research.

Mr. Neil Flanzraich, age 58, has served as a director since the merger and had served as a director of the pre-merger Diagnostics since September 1998. He has served as Vice Chairman and President of IVAX since May 1998 and as a director of IVAX since 1997. He was a stockholder and served as Chairman of the Life Sciences Legal Practices Group of Heller Ehrman White & McAuliffe from 1995 to May 1998. From 1981 to 1994, he served in various capacities at Syntex Corporation (pharmaceuticals), most recently as its Senior Vice President, General Counsel and a member of the Corporate Executive Committee. From 1994 to 1995, after Syntex Corporation was acquired by Roche Holding Ltd., he served as Senior Vice President and General Counsel of Syntex (U.S.A.) Inc., a Roche subsidiary. He is a director of Whitman Education Group, Inc. (proprietary education) and Continucare Corporation (integrated health care).

Dr. Jane Hsiao, age 54, has served as a director since the merger. She has served as IVAX' Vice Chairman-Technical Affairs since February 1995, as IVAX' Chief Technical Officer since July 1996, and as Chairman and Chief Executive Officer of DVM Pharmaceuticals, Inc., IVAX' veterinary products subsidiary, since March 1998. From 1992 until February 1995, she served as IVAX' Chief Regulatory Officer and Assistant to the Chairman, and as Vice President-Quality Assurance and Compliance of Baker Norton Pharmaceuticals, Inc., IVAX' principal proprietary pharmaceutical subsidiary. From 1987 to 1992, Dr. Hsiao was Vice President-Quality Assurance, Quality Control and Regulatory Affairs of Baker Norton Pharmaceuticals, Inc.

Dr. John Harley, age 52, has served as a director since the merger. He has held various positions at the University of Oklahoma Health Sciences Center since 1982. In the Department of Medicine, his positions include Chief of Rheumatology, Allergy and Immunology Section and Vice Chair for Research, George Lynn Cross Research Professor (1999 to present). James R. McEldowney Chair in Immunology and Professor of Medicine (1992 to present), Associate Professor (1986 to 1992), and Assistant Professor (1982 to 1986). Since 1996 Dr. Harley has been an Adjunct Professor in the Department of Pathology. In the Department of Microbiology, Dr. Harley has served as Adjunct Professor (1992 to present), Adjunct Associate Professor (1988 to 1992), and Adjunct Assistant Professor (1983 to 1988). Since 1982 Dr. Harley has also been associated with the Oklahoma Medical Research Foundation's Arthritis and Immunology Program as Program Head (1999 to present), Member (1998 to present), Associate Member (1989 to present), Affiliated Associate Member (1986 to 1989), and Affiliated Assistant Member (1982 to 1986). Dr. Harley has also served as a Staff Physician (1982, to 1984 to 1987 and 1992 to present), and a Clinical Investigator (1987 to 1992), Immunology Section, Medical Service at the Veterans Administration Medical Center, Oklahoma City, Oklahoma. In 1981 and 1982, Dr. Harley was a Postdoctoral Fellow in Rheumatology with the Arthritis Branch of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, National Institute of Health, Bethesda, Maryland. He was also a Clinical Associate at the Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland from 1979 to 1982.

Dr. Jack Borsting, age 73, has served as a director since the merger. From 1994 to the present, he has served as the E. Morgan Stanley Professor of Business Administration at the University of Southern California. From 1995 to 2002, Dr. Borsting was the Executive Director of the Center for Telecommunications Management at the University of Southern California. From 1988 to 1994, he was Dean and Professor of Business Administration at

the University of Southern California, Los Angeles. From 1983 to 1988, he was Dean of the University of Miami School of Business Administration. Dr. Borsting is a director of Whitman Education Group, Inc. (proprietary education). Dr. Borsting is a trustee of the Institute for Defense Analysis, the Rose Hill Foundation and the Los Angeles Orthopedic Hospital Foundation and MetLife Investors.

Randall K. Davis, age 38, has served as a director since the merger and had served as a director of b2bstores prior to the merger since May 2000. Mr. Davis is the Chairman of the Board, Chief Executive Officer and President of Titanium Holdings Group, Inc. (formerly known as Enviro-Clean of America, Inc.) (manufacturer and distributor of janitorial supplies). From May 1985 until July 1999, Mr. Davis was the co-owner, President and Chief Executive Officer of Cleaning Ideas, Inc., whose holdings included Sanivac, Inc. and Davis Manufacturing Company (manufacturers of commercial cleaning products).

Jay Raubvogel, age 52, has served as a director since the merger and had served as a director of b2bstores prior to the merger since March 2000. Mr. Raubvogel was the Chief Executive Officer of Baker's Aid, Inc. (food service equipment manufacturers) from 1985 to 1994. Mr. Raubvogel has been a private investor. Mr. Raubvogel serves as a trustee of North Shores L.I.J. Health Systems and Vice-Chairman of its Foundation.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and 10% shareholders to file initial reports of ownership and reports of changes in ownership of common stock and other of our equity securities with the Securities and Exchange Commission and the American Stock Exchange. Directors, executive officers and 10% shareholders are required to furnish us with copies of all Section 16(a) reports they file. Based on a review of the copies of such reports furnished to us and written representations from our directors and executive officers that no other reports were required, we believe that our directors, executive officers and 10% shareholders complied with all Section 16(a) filing requirements applicable to them for the year ended December 31, 2001.

## Item 11. *Executive Compensation*

### Executive Compensation

The following table contains certain information regarding aggregate compensation paid or accrued by us during 2001, 2000 and 1999 to the Chief Executive Officer and to each of our other highest paid executive officers other than the Chief Executive Officer whose total annual salary and bonus exceed $100,000.

**SUMMARY COMPENSATION TABLE**

| | | | | | Long Term Compensation | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Awards | | Payouts | |
| | | Annual Compensation | | | Shares | | | |
| Name and Principal Position | Year | Salary($) | Bonus($) | Other Annual Compen-sation($) | Restricted Stock Award(s)($) | Underlying Stock Options(#) | Long-Term Incentive Plan Payouts($) | All Other Compensation($) |
| Giorgio D'Urso | 2001(1) | $279,770 | — | — | — | — | — | — |
| Chief Executive | 2000 | $348,519 | $20,000 | — | — | — | — | — |
| Officer | 1999 | $348,987 | $17,426 | — | — | 600,000 | — | $118,375 |
| Mark Voorhis(2) | 2001 | $ 35,000 | — | — | — | — | — | $161,000(3) |
| Chief Executive | 2000 | — | — | — | — | — | — | — |
| Officer | 1999 | — | — | — | — | — | — | — |
| Duane M. Steele | 2001(4) | $112,254 | — | — | — | 50,000 | — | — |
| Vice President– | 2000 | $132,824 | $18,550 | — | — | — | — | — |
| Business Development | 1999 | $122,237 | $ 6,250 | — | — | 120,000 | — | — |

* Value of perquisites and other personal benefits paid does not exceed the lesser of $50,000 or 10% of the total annual salary and bonus reported for the executive officer.

(1) Does not include $68,749 in salary and $20,000 in bonus paid to Mr. D'Urso in 2001 prior to the merger by the pre-merger Diagnostics.

(2) Mr. Voorhis served as the Chief Executive Officer of b2bstores prior to the merger.

(3) Mr. Voorhis received $161,000 as a severance payment in connection with the merger.

(4) Does not include $27,584 in salary and $18,000 in bonus paid to Mr. Steele in 2001 prior to the merger by the pre-merger Diagnostics.

### Stock Options

The following table sets forth information concerning stock option grants made during 2001 to the executive officers named in the "Summary Compensation Table."

**STOCK OPTION GRANTS IN FISCAL YEAR 2001**

| | Individual Grants | | | | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term | |
|---|---|---|---|---|---|---|
| Name | Shares Underlying Stock Options Granted(#) | % of Total Options Granted to Employees | Exercise Price ($/Sh) | Expiration Date | 5%($) | 10%($) |
| Giorgio D'Urso ..... | — | — | — | — | — | — |
| Mark Voorhis ..... | — | — | — | — | — | — |
| Duane M. Steele ..... | 50,000 | 20% | $3.00 | March 2008 | $61,065 | $142,308 |

The following table sets forth information concerning stock option exercises during 2001 by each of the executive officers named in the "Summary Compensation Table" and the year-end value of unexercised options held by such officers and does not include any stock option exercises for shares of IVAX under the IVAX 1997 Employee Stock Option Plan.

**STOCK OPTION EXERCISES IN FISCAL YEAR 2001 AND FISCAL YEAR-END OPTION VALUES**

| | | | Number of Shares Underlying Unexercised Stock Options at Fiscal Year-End(#) | | Value of Unexercised In-the-Money Stock Options at Fiscal Year-End($) | |
|---|---|---|---|---|---|---|
| Name | Shares Acquired on Exercise(#) | Value Realized($) | Exercisable | Unexercisable | Exercisable | Unexercisable |
| Giorgio D'Urso ..... | — | — | 300,000 | 300,000 | $825,000 | $825,000 |
| Mark Voorhis ..... | — | — | 183,333 | — | $ 7,666 | — |
| Duane M. Steele ..... | — | — | 60,000 | 110,000 | $165,000 | $189,000 |

### Employment Contracts and Termination of Employment and Change-in-Control Arrangements

On October 1, 1998, the pre-merger Diagnostics entered into a five-year employment agreement with Giorgio D'Urso, President and Chief Executive Officer, at a base annual salary of $348,519, with discretionary annual adjustments. We assumed this employment agreement by operation of law in the merger. Mr. D'Urso's employment may be terminated with or without cause at any time upon written notice. For a termination without cause, we must pay Mr. D'Urso his then current annual base salary in installments for the remainder of the employment term. While employed by us and for a two-year period thereafter, Mr. D'Urso cannot employ or

contract with any of our current employees or former employees, except former employees who have not been employed by us for more than one year.

### Compensation Committee Interlocks and Insider Participation

The members of the Compensation and Stock Option Committee of the Board of Directors are Neil Flanzraich, John Harley, M.D., and Jay Raubvogel.

## Item 12. *Security Ownership of Certain Beneficial Owners and Management*

The following table indicates, as of March 20, 2002, information about the beneficial ownership of our common stock by (1) each director, (2) each executive officer named in the "Summary Compensation Table," (3) all directors and executive officers as a group, and (4) each person who we know beneficially owns more than 5% of our common stock. All such shares were owned directly with sole voting and investment power unless otherwise indicated.

| Name | Shares(#)(1) | Percent of Class(%) |
|---|---|---|
| IVAX Corporation<br>4400 Biscayne Boulevard<br>Miami, Florida 33137 | 20,000,000 | 69.9% |
| Randall K. Davis<br>1023 Morales Street<br>San Antonio, Texas 78207 | 1,666,833(2) | 5.8% |
| Steven Etra<br>5830 57th Street<br>Maspeth, New York 11378 | 1,462,824(3) | 5.1% |
| Giorgio D'Urso | 315,00(4) | 1.1% |
| Duane M. Steele | 60,000(5) | * |
| Mark Deutsch | 18,000(6) | * |
| Phillip Frost, M.D. | 39,500(7) | * |
| Neil Flanzraich | 5,000(8) | * |
| Jane Hsiao, Ph.D. | 5,000(9) | * |
| John Harley, M.D. | 5,000(10) | * |
| Jack Borsting, Ph.D. | 5,500(11) | * |
| Jay Raubvogel | 190,000(12) | * |
| Mark Voorhis | 183,333(13) | * |
| All directors and executive officers as a group (11 persons) | 2,493,166 | 8.7% |

* Represents beneficial ownership of less than 1%.

(1) For purposes of this table, beneficial ownership is computed pursuant to Rule 13d-3 under the Securities Exchange Act of 1934.

(2) Includes (a) options for 105,000 shares of common stock granted to Mr. Davis and (b) 1,288,500 shares of common stock owned by Titanium Holdings Group, Inc. (formerly known as Enviro-Clean of America, Inc.), a corporation in which Mr. Davis serves as the Chairman of the Board, Chief Executive Officer and President. In a filing with the SEC, Mr. Davis disclaimed beneficial ownership of the securities held by Titanium Holdings Group, Inc., except to the extent of his pecuniary interest.

(3) Includes (a) 10,667 shares of common stock owned by SRK Associates L.L.C., a company controlled by Mr. Etra, (b) 1,000 shares of common stock owned by Lances Property Development Pension Plan, which is 50% owned by Mr. Etra, (c) 1,228,500 shares of common stock owned by Titanium Holdings Group, Inc. (formerly known as Enviro-Clean of America, Inc.), a corporation in which Mr. Etra is a shareholder and a director, and (d) 3,500 shares of common stock owned by Gemini Capital L.L.C., a company in which Mr. Etra is the Secretary, a director and a shareholder. In a filing with the SEC, Mr. Etra disclaimed beneficial ownership of the securities held by SRK Associates L.L.C., Lances Property Development Pension Plan, Titanium Holdings Group, Inc., and Gemini Capital L.L.C., except to the extent of his pecuniary interest.
(4) Includes options for 300,000 shares of common stock granted to Mr. D'Urso.
(5) Includes options for 60,000 shares of common stock granted to Mr. Steele.
(6) Includes options for 18,000 shares of common stock granted to Mr. Deutsch.
(7) Includes (a) options for 5,000 shares of common stock granted to Dr. Frost and (b) 34,500 shares of common stock owned by Frost Gamma LP, a limited partnership in which Dr. Frost is the sole limited partner and in which Dr. Frost is the sole shareholder of Frost—Nevada Corp., the sole shareholder of Frost Gamma, Inc., the general partner. Does not include any securities owned by IVAX Corporation, a corporation in which Dr. Frost is the Chairman of the Board and Chief Executive Officer, and Dr. Frost disclaims beneficial ownership of securities held by IVAX Corporation.
(8) Includes options for 5,000 shares of common stock granted to Mr. Flanzraich.
(9) Includes options for 5,000 shares of common stock granted to Dr. Hsiao.
(10) Includes options for 5,000 shares of common stock granted to Dr. Harley.
(11) Includes options for 5,000 shares of common stock granted to Dr. Borsting.
(12) Includes options for 150,000 shares of common stock granted to Mr. Raubvogel.
(13) Includes options for 183,333 shares of common stock granted to Mr. Voorhis.

**Item 13.** ***Certain Relationships and Related Transactions***

Upon completion of the merger, we entered into a registration rights agreement with IVAX that requires us to file a registration statement on Form S-3 (at any time after one year, and before the earlier of five years following the completion of the merger or such time at which all the shares of our common stock owned by IVAX can be sold in any three-month period without registration) to register not less than $1.0 million of our common stock owned by IVAX. Additionally, IVAX may "piggyback" on registrations initiated by us or other holders exercising similar demand registration rights. We may delay the filing of any registration statement for 120 days if we determine in good faith that to effect such registration statement would be detrimental to us or our stockholders. We have agreed to pay all fees and expenses in connection with such registrations, except for any underwriting discounts and commissions. If we file a registration statement in connection with an underwritten offering, IVAX has agreed to sign a customary underwriting agreement in connection with such registration and its rights to register shares is subject to a proration provision if the underwriters determine that the success of the offering will be jeopardized from too many shares being included in the offering. Shares to be sold by us on any registered offering will be included prior to the inclusion of any other shares of our common stock held by IVAX. The registration rights agreement also contains customary mutual indemnification and market stand-off provisions. IVAX can assign or transfer its rights under the registration rights agreement.

In connection with the merger, we entered into a shared services agreement with IVAX pursuant to which IVAX would continue to provide administrative and management services previously provided by IVAX to the pre-merger Diagnostics prior to the merger at IVAX' cost plus 15% for a period of three months. These services include payroll, including printing paychecks and making associated tax filings; treasury, including cash management services such as disbursements, receipts, banking and investing; insurance, including procuring and administering policies; human resources, including administering employee benefits and plans; financial reporting, including public reports, income taxes; and information systems, including network and website hosting, phone and data systems, software licenses and information systems support.

In connection with the merger, we entered into a use of name license with IVAX that grants us a non-exclusive, royalty free license to use the name "IVAX." The license was not terminable by IVAX for a one-year period. After the first year, IVAX may terminate the license upon 90 days' written notice. Upon termination of the agreement, we must take all steps reasonably necessary to change our name as soon as is practicable. If IVAX abandons its use of the name, IVAX must transfer all rights to the name to us. The termination of this agreement by IVAX could have a material adverse affect on our ability to market our products and on us.

Giulio D'Urso, the son of our Chief Executive Officer and President, has been engaged by our subsidiaries and us for annual compensation of $120,000.

## PART IV

**Item 14.** ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a) Documents Filed as Part of this Annual Report on Form 10-K:

(1) Financial Statements

The following consolidated financial statements of IVAX Diagnostics, Inc. and its subsidiaries are included in Part II, Item 8 of this Annual Report on Form 10-K:

Report of Independent Certified Public Accountants

Consolidated Balance Sheets as of December 31, 2001 and 2000

Consolidated Statements of Operations for each of the three years in the period ended December 31, 2001

Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 2001

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2001

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

Schedules have been omitted because the required information is not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits

The following exhibits are either filed as a part of this Annual Report on Form 10-K or are incorporated into this Annual Report on Form 10-K by reference to documents previously filed as indicated below:

| Exhibit Number | Description | Method of Filing |
|---|---|---|
| 3.1(a) | Certificate of Incorporation | Incorporated by reference to our Form SB-2 dated October 6, 1999. |
| 3.1(b) | Certificate of Amendment to Certificate of Incorporation | Incorporated by reference to our Form SB-2/A dated December 2, 1999. |
| 3.1(c) | Certificate of Merger | Filed herewith. |
| 3.2 | Amended and Restated Bylaws | Filed herewith. |
| 4.1 | Specimen Common Stock Certificate | Filed herewith. |
| 4.2 | Form of Representatives' Warrant Agreement and Form of Representatives' Warrant Certificate | Incorporated by Reference to our Form SB-2/A dated January 26, 2000. |
| 4.3 | Registration Rights Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation | Filed herewith. |
| 10.1 | Merger Agreement, dated November 21, 2000, between IVAX Corporation, IVAX Diagnostics, Inc. and b2bstores.com Inc. | Incorporated by reference to our Schedule 14A dated January 30, 2001. |
| 10.2 | Distributor Agreement, dated October 12, 2000, between IVAX Diagnostics, Inc. and Sigma Diagnostics, Inc. | Filed herewith. |
| 10.3 | Distributorship Agreement, dated April 26, 1999, between IVAX Diagnostics, Inc. and Sigma Diagnostics, Inc. | Filed herewith. |
| 10.4 | Consulting Agreement, dated September 1, 1999, between IVAX Diagnostics, Inc. and Mario Cossi | Filed herewith. |
| 10.5 | Assignment and Royalty Agreement, dated December 12, 1994, between Diamedix Corporation, Mario Cossi and Riccardo Cossi, as amended as of February 1, 1997, September 1, 1999, and February 15, 2001 | Filed herewith. |
| 10.6 | Use of Name License Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation | Filed herewith. |
| 10.7 | Shared Services Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation | Filed herewith. |
| 10.8 | Employment Agreement, dated October 1, 1998, between IVAX Diagnostics, Inc. and Giorgio D'Urso | Filed herewith. |
| 10.9 | 1999 Performance Equity Plan | Incorporated by reference to our Form SB-2 dated October 6, 1999. |
| 10.10 | 1999 Stock Option Plan | Filed herewith. |
| 21.1 | Subsidiaries of IVAX Diagnostics, Inc. | Filed herewith. |
| 23.1 | Consent of Arthur Andersen LLP | Filed herewith. |
| 99.1 | Letter to Securities and Exchange Commission Regarding Arthur Andersen LLP | Filed herewith. |

(b) Reports On Form 8-K

We did not file any reports on Form 8-K during the quarter ended December 31, 2001.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IVAX DIAGNOSTICS, INC.

Dated: April 1, 2002

By: /s/ GIORGIO D'URSO
**Giorgio D'Urso**
**Chief Executive Officer**
**and President**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Name | Capacity | Date |
|---|---|---|
| /s/ GIORGIO D'URSO<br>**Giorgio D'Urso** | Chief Executive Officer, President and Director (Principal Executive Officer) | April 1, 2002 |
| /s/ MARK DEUTSCH<br>**Mark Deutsch** | Chief Financial Officer and Vice President—Finance (Principal Financial Officer) (Principal Accounting Officer) | April 1, 2002 |
| /s/ PHILLIP FROST, M.D.<br>**Phillip Frost, M.D.** | Chairman of the Board of Directors | April 1, 2002 |
| /s/ NEIL FLANZRAICH<br>**Neil Flanzraich** | Director | April 1, 2002 |
| /s/ JANE HSIAO, PH.D.<br>**Jane Hsiao, Ph.D.** | Director | April 1, 2002 |
| /s/ JOHN HARLEY, M.D.<br>**John Harley, M.D.** | Director | April 1, 2002 |
| /s/ JACK BORSTING, PH.D.<br>**Jack Borsting, Ph.D.** | Director | April 1, 2002 |
| /s/ RANDALL K. DAVIS<br>**Randall K. Davis** | Director | April 1, 2002 |
| /s/ JAY RAUBVOGEL<br>**Jay Raubvogel** | Director | April 1, 2002 |

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We have made forward-looking statements in this annual report. Forward-looking statements may be preceded by, followed by, or otherwise include the words "believe," "expect," "anticipate," "intend," "plan," "estimate," "project," "would," "should," or similar expressions or statements that certain events or conditions "may" occur. Actual results or performance could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on our expectations and the beliefs and assumptions of our management and on the information currently available to them and are subject to a number of risks and uncertainties, including, but not limited to, the risks and uncertainties associated with: economic, competitive, political, governmental and other factors affecting us and our operations, markets and products; our ability to provide innovative and proprietary testing systems throughout the world in the immunology market sector enabling laboratories to perform laboratory testing in an efficient and automated manner; the success of technological, strategic and business initiatives, including, without limitation, our ability to timely develop and commercially market a new instrument system; the success of our marketing and sales efforts; our ability to increase the number of sales personnel; our ability to grow our market share; success at marketing products directly without Sigma Diagnostics; our ability to find or enter into strategic acquisitions and technology agreements; our ability to consummate potential acquisitions of businesses or products; integrating acquired assets, businesses or products, including, without limitation, Sigma Diagnostics' EIA product line; creating and utilizing synergies from acquired assets, businesses or products, including, without limitation, in connection with our acquisition of Sigma Diagnostics' EIA product line; our limited operating revenues and history of operating losses; and other factors discussed elsewhere in our periodic filings with the SEC, including, without limitation, in our Form 10-K which has been provided as a portion of this annual report. Many of these factors are beyond our control.


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**www.ivaxdiagnostics.com**